TECHNICAL DOCUMENT

Assessing communicable disease control and prevention in EU enlargement countries

Disease surveillance, preparedness and response, health governance and public health capacity development

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This technical document of the European Centre for Disease Prevention and Control (ECDC) was developed by the Task Force for Enlargement countries assessment, chaired by Maarit Kokki and coordinated by Bogusław Suski.

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Introduction

ECDC has been working with EU Candidate Countries[1] since 2006 and with EU Potential Candidate Countries[2] since 2009 to prepare them for participation in ECDC activities. Work with these countries has been mainly financed by a Contribution Agreement between the Directorate-General for Neighbourhood and Enlargement Negotiations (DG NEAR) and ECDC under the Instrument for Pre-accession Assistance (IPA). Enlargement countries are required to adopt and implement the EU acquis. Strengthening their administrative, institutional, and prevention and control capacities with regard to communicable diseases is part of this process and falls within the remits of ECDC[3].

A country that wishes to join the EU, submits an application for EU membership to the European Council[4], which asks the European Commission to assess the applicant's ability to meet the necessary EU requirements and a core set of accession criteria. It is important that an enlargement country makes EU law part of its own national legislation. It is equally important that the country develops appropriate administrative and institutional structures to implement and enforce this legislation. The Commission evaluates the progress made by enlargement countries at regular intervals.

To evaluate progress in the area of communicable diseases, the European Commission's Directorate-General Health and Food Safety (DG SANTE) has requested ECDC to develop methodologies and tools for assessing the capacity development, surveillance, preparedness and response, and health governance in this domain for all EU enlargement countries (EU Candidate Countries and Potential Candidates). Following this request, ECDC developed and tested a set of tools which now constitute a complete assessment package (see Annexes).

DG SANTE uses ECDC's assessment of a (Potential) Candidate Country's capacity in the area of communicable diseases to contribute to the annual EU enlargement progress report.

Based on the results of their evaluations and assessments, ECDC and DG SANTE will provide guidance to the enlargement countries on how to strengthen communicable disease prevention and control systems and how to ensure the systems' sustainability.

Purpose

The purpose of this document is to establish a framework for the assessment process and to provide a toolkit to conduct this assessment. All toolkit documents are provided in the Annexes.

In this context, the term 'toolkit' refers to a set of tools which can be found in the various annexes to this document: a list of pertinent EU acquis and other documents which contain standards in the area of communicable diseases (Annex 1), the architecture of the assessment documents (Annex 2), the methodology used for planning missions to enlargement countries, including practical tips for itinerary planning and evaluation strategies (Annex 3), a self-assessment questionnaire to be filled in by the enlargement country before the visit of the assessment team, complete with instructions and definitions (Annex 4), a set of practical guidelines for assessment teams conducting a visit to an enlargement country (Annex 5), and, finally, a template for the assessment team's technical assessment report (Annex 6).

Objectives of the assessment process

The assessment process outlined in this document is an essential component of the working relationship between ECDC and the EU enlargement countries. It aims at further strengthening the national systems for communicable disease prevention and control. The overall process is guided by three main objectives:

- To identify achievements and possible gaps in current communicable disease surveillance and prevention and control systems, and to stimulate the development of sustainable systems in enlargement countries.
- To prepare the country for efficient collaboration with ECDC, for example in the area of disease reporting).
- To provide comprehensive information to the European Commission on an enlargement country's compliance with, and implementation of, EU legislation, and on capacity building in the area of communicable diseases.

[1] At current, Albania, the former Yugoslav Republic of Macedonia, Montenegro, Serbia, and Turkey are EU Candidate Countries.

[2] EU Potential Candidates: Bosnia and Herzegovina, Kosovo*
* This designation is without prejudice to positions on status, and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo Declaration of Independence.

[3] ECDC Management Board Meeting 20/12 – ECDC draft policy on collaboration with 'third countries'

[4] http://ec.europa.eu/enlargement/index_en.htm

The assessment process was designed to answer the following questions:

- Does the country have provisions that allow for the full implementation of the EU acquis with regard to the communicable disease system?
- Does the country have the infrastructure in place to implement the EU acquis and related recommendations/best practise in the field of communicable diseases?
- Does the country have the administrative capacities – including human resources, technical equipment, and sustainable funding – to implement the EU acquis and related recommendations/best practise in the area of communicable diseases?
- Does the surveillance of communicable diseases meet EU standards with regard to epidemiologic data on all diseases under EU surveillance, their case definitions and reporting protocols?
- Does the preparedness and response system in the area of public health emergencies (including communicable diseases) meet the EU standards in preparedness, and is there sufficient institutional capacity to timely provide comparable data and participate in coordinated activities organised by ECDC and other EU bodies?

Based on the outcomes of the assessment, the assessment team will produce a technical assessment report which includes recommendations for further improvements aimed at the full implementation of the EU communicable disease legislation and strengthening of administrative and institutional capacity. The European Commission/DG SANTE will analyse the report and evaluate the country's progress. The information obtained will contribute to the annual reporting cycle on the enlargement progress and will be used to advise the enlargement country on how to develop a sustainable public health system for communicable diseases.

Assessment areas

The assessment of enlargement countries covers the following areas and elements:

Health governance

- Legislation
- Organisational structures, institutional and financial sustainability of the system
- Future participation of the country in the EU structures

Human resource capacity development

- Capacity in applied/field epidemiology
- Training and education
- Curricula for specialisation or post-graduate training in applied epidemiology, clinical microbiology and related specialties
- Continuing professional development regarding communicable disease surveillance and response functions
- Licensing of medical workforce

Surveillance

- Description of National surveillance system
- Surveillance system assessment
- System coordination and integration
- Outbreak detection and control
- Response to national or high-risk outbreaks of communicable diseases
- Epidemic intelligence

Preparedness for, and response to, public health emergencies

- Management of preparedness plans
- Coordination structures for cross-sectoral incidents
- Strategic and operational coordination of serious cross-border threats to health
- Business continuity planning associated with serious cross-border threats to health
- Capacities to anticipate, respond to, and recover from the impacts of likely, imminent or current crises at all levels (governmental, communities, professional and recovery organisations, individuals).
- International reporting
- Risk communication

National system of public health microbiology laboratories

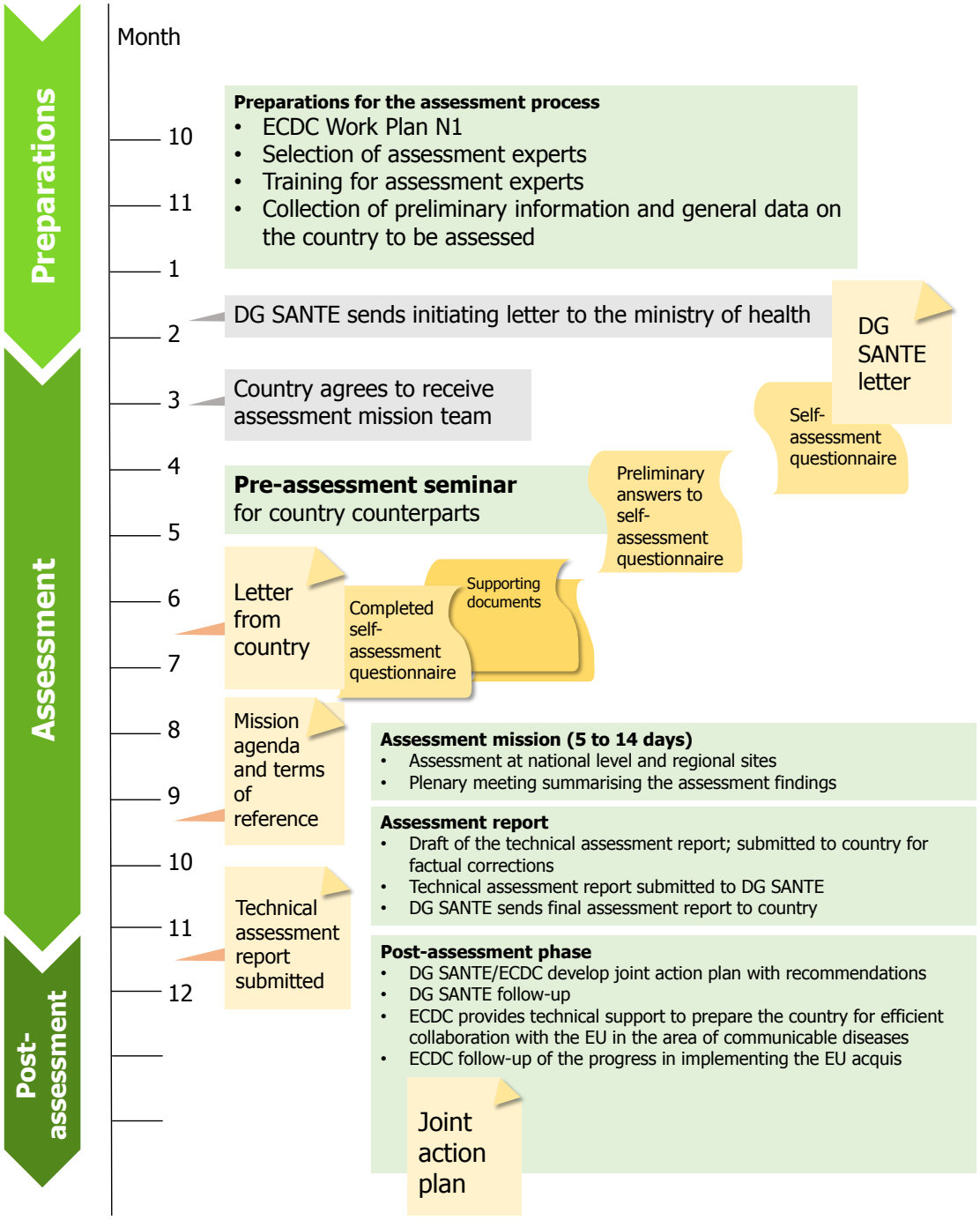
- Public health microbiology laboratory – system description
- Primary microbiology laboratory services
- Reference microbiology laboratory services
- Laboratory biosafety regulation, certification and auditing

- Public health microbiology laboratory support to outbreak alert, investigation and response
- Business continuity for public health microbiology services

Disease programmes

- Antimicrobial resistance and healthcare-associated infections Programme (ARHAI),
- HIV, sexually transmitted infections and viral hepatitis programme (HIMH)
- Tuberculosis programme (TB)
- Influenza and other respiratory viruses programme (IRV)
- Food- and waterborne diseases and zoonoses programme (FWD)
- Emerging and vector-borne diseases programme (EVD)
- Vaccine-preventable diseases programme (VPD)

Figure 1. Flowchart of the assessment process



Assessment process: coordination and communication

At the technical level, the assessment process is coordinated by representatives of the European Commission, ECDC experts, and a country official appointed by national authorities. All three parties also provide the appropriate mechanisms for information flow and correspondence.

The EU Delegation in the assessed enlargement country is kept informed about the official correspondence and receives regular updates on the assessment process.

ECDC's International Relation Section coordinates all assessment activities, both internally and externally.

Enlargement countries participating in the assessment process should upload the completed self-assessment questionnaire (Annex 4) plus all supporting documents to the ECDC extranet (ANECC). A copy should be e-mailed to:

SANTE-ECDC-INTERNATIONAL@ec.europa.eu; International.Relations@ecdc.europa.eu

Hard copies of all documents should be marked 'Country capacity assessment' on the envelope and mailed to DG SANTE and ECDC.

European Commission
Office B232/09
B-1049 Brussels
Belgium

European Centre for Disease Prevention and Control
Director's Office
Granits väg 8, 171 65 Solna,
Sweden

Detailed instructions are available in Annex 4.

Preparations for the assessment process

- ECDC forms a **group of assessment experts** – consisting of ECDC and national experts in capacity development, surveillance, preparedness and response, and/or health governance in the field of communicable diseases.
- ECDC organises a **training course for assessment experts**. Topics include the assessment process and its scope, objectives and timelines, assessment methodology, tools, and documents. Experts from the Commission are invited to provide an overview of the EU enlargement process, relevant EU acquis, and the role of the Commission. ECDC provides all additional trainers.
- During the preparatory phase, ECDC collects up-to-date information on the enlargement country's national public health system and other pertinent data. In addition, DG SANTE provides country-specific information collected as part of the enlargement process. All this information is provided as background documentation to the assessment team.

Initiation of the assessment process

- The European Commission/DG SANTE initiates the assessment process with an official letter to the public health authorities in an enlargement country. During the assessment, the Commission remains in charge of the overall assessment. The Commission requests a country's assent to participate in the assessment and to provide all relevant information as required by the self-assessment questionnaire, which will be attached to the communication.
- ECDC appoints the technical **assessment team**, composed of experts from ECDC and external organisations. Pending availability and time, the team will be accompanied by European Commission officials. WHO representatives may participate, as appropriate.
- The team composition ensures the **necessary expertise**, covering health governance, education and training in epidemiology and microbiology, communicable disease surveillance, including IT/TESSy expertise, preparedness and response, public health microbiology, administration, and international cooperation.
- Two months before the planned assessment mission, ECDC organises a **pre-assessment seminar** to familiarise the appointed experts in the enlargement country with the EU acquis requirements, relevant ECDC standards, and best practices used in EU Member States. During the seminar, participants discuss the overall assessment process, the assessment toolkit, assessment methodology, and the assessment timeline. Commission officials are invited to provide an overview of the EU acquis and the enlargement process. If possible, a separate session will be organised for Commission representatives to discuss compliance with the EU acquis. On the basis of the self-assessment questionnaire, representatives of the enlargement

country are invited to present their national public health systems and pre-accession activities in this area. The pre-assessment seminar marks, for all practical purposes, the start of the **assessment process**.

Assessment process

The enlargement country's national system of communicable disease surveillance and control will be assessed against the requirements of the EU acquis, ECDC standards and good practices in EU Member States. A list of the documents pertinent to these requirements is provided in Annex 1.

The assessment of enlargement countries is done with the help of the evaluation grid in Annex 2. In this grid, each element of a country's public health system is linked to a document which contains the requirements against it should be assessed.

The assessment process consists of several steps and follows the timeline in Figure 1.

- The public health authorities and competent institutions in the enlargement country first complete a **self-assessment questionnaire** (Annex 4[5]). This questionnaire provides ECDC and the Commission with a good understanding of the national communicable disease prevention and control system, its organisational structure and functions, relevant national legislation and key developments in the area. Country authorities are expected to send the completed self-assessment questionnaire within two month from the request to the Commission and ECDC, along with the required supporting documents.
- Within a month of receiving the completed self-assessment questionnaire, the **information is analysed** in accordance with the methodology described in Annex 3. In addition to the questionnaire, the assessors also analyse information from documents provided by the enlargement country and from published reports by relevant international organisations. A third source of information are the answers received in response to specific enquiries of the assessment team.
- The analysis of these strands of information makes it possible to prepare specific check lists and semi-structured interviews for use during the country visit. Particular attention is given to the patient and information flow within the health system and how each aspect of the system functions and relates to other aspects. Throughout the entire duration of the country review, 'system test cases' are consistently used as 'acid tests'.
  A provisional system assessment is drafted based on the information available before the actual country visit.
- In parallel to the activities described above, ECDC, together with its counterparts in the enlargement country, finalises the itinerary and agenda of the assessment mission to the enlargement country. The **practical guidelines for the assessment mission** to the enlargement country in Annex 5 provide a set of supporting documents which facilitate the preparation of the visit. The Annex also includes **terms of reference** (ToR) for the assessment country mission, which should be agreed upon with the country counterparts one week before the mission. The ToR specify all relevant details, such as the objectives of the visit and assessment process, the duration of the visit, and the programme of the visit.
- The **country assessment mission** has two general objectives: The first objective is to verify, refine or correct the data and information gathered from the self-assessment questionnaire and pre-assessment research. This is necessary to correctly understand the strengths and achievements of the country in the assessment areas, to gather more practical information on how the national system functions (e.g. through case studies, mock-up exercises or reality-check activities). Objective two is to identify areas for further improvement and discuss the enlargement country's collaboration with the EU, the European Commission and ECDC.
  The standard duration of an assessment mission to an enlargement country is five working days. This should include time allocated to areas outside the capital in order to ensure a complete picture of all available services in the area of communicable diseases. Ideally, at least two different regional sites should be chosen in consultation with the country. Selection criteria should include geography, logistics, and the comparability of the statistical data. In larger countries with many districts, a sampling method may be employed, in accordance with the methods described in Annex 3.

Assessment report

- After the mission, the assessment team **drafts a technical assessment report** based on the data and information gathered during the process, including the self-assessment questionnaire and the country assessment visit. The report will follow the template enclosed in Annex 6. The report should contain

[5] Annex 4 is available as a separate download from http://ecdc.europa.eu/en/aboutus/Partnerships/Pages/Assessment-of-enlargement-countries.aspx

assessment **recommendations** which address all areas for improvement in the national communicable disease system.

- Three months after the mission, ECDC presents the draft technical report to the assessed EU enlargement country, asking for factual corrections. After correcting the draft, the **technical assessment report** is sent to the Commission for analysis. The Commission provides the country with the final **assessment report**. The report can be published subject to the agreement of the assessed country and the European Commission.

Post-assessment phase

The assessment team's recommendations in the technical assessment report are used:

- by the assessed country to create an action plan for improvement of the communicable disease system, the implementation of legislation, and strengthening of administrative capacity;
- by the European Commission to identify suitable ways of the EU assistance, including EU financing instruments to improve the communicable disease system; and
- by ECDC to provide a context for its ongoing technical relationship with country system leaders, including identification of technical assistance to the country, within its remits and available financial and human resources.

The Technical Assessment Reports serve as reference documents for assessing the progress made by the countries in the pre-accession period and contribute to the public health section of the enlargement progress reports[6].

[6] Enlargement progress reports are available from: http://ec.europa.eu/enlargement/countries/check-current-status/index_en.htm

Annex 1. EU acquis and documents containing standards in the area of communicable diseases

EU *acquis communautaire* on communicable disease surveillance, prevention and control

Article 168 Public Health of the treaty on the functioning of the European Union

Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC; OJ L 2013 293, 5.11.2013

Commission Decision 2000/96/EC of 01 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council; OJ L 28, 3.2.2000

Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council; OJ L 21/32; 26.01.2000

Commission Decision 2002/253/EC of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council; OJ L 86/44; 03.04.2002

Commission Implementing Decision 2012/506/EU of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council; OJ L 262, 27.9.2012, p. 1–57

Commission Decision 2012/492/EU of 3 September 2012 amending Decision 2000/96/EC as regards tick-borne encephalitis and the category of vector-borne communicable diseases; OJ L 239, 5.9.2012, p. 3–4

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; OJ L 142/1;30.04.2004

Commission Decision 2009/547/EC of 10 July 2009 amending Decision 2000/57/EC on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council; OJ L 181/57, 11 July 2009

Commission Decision 2009/539/EC of 10 July 2009 amending Decision 2000/96/EC on communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council; OJ L 180/20; 11 July 2009

Commission Decision 2009/312/EC of 02 April 2009 amending Decision 2000/96/EC as regards dedicated surveillance networks for communicable diseases; OJ L 91/27; 03.04.2009

Commission Decision 2008/351/EC of 28 April 2008 amending Decision 2000/57/EC as regards events to be reported within the early warning and response system for the prevention and control of communicable diseases; OJ L 117/40; 01.05.2008

Commission Decision 2007/875/EC of 18 December 2007 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions; OJ L 344/48; 28.12.2007

Commission Decision 2003/542/EC of 17 July 2003 amending Decision 2000/96/EC as regards the operation of dedicated surveillance networks; OJ L 185/55; 24.07.2003

Council Recommendation 2002/77/EC of 15 November 2001 on the prudent use of antimicrobial agents in human medicine

Directive 2003/99/EC on the monitoring of zoonozes and zoonotic agents, 17 November 2003

Regulation 2160/2003/EC on the control of salmonella and other specified food-borne zoonotic agents, 17 November 2003

Council Recommendation 2009/1019/EC of 22 December 2009 on seasonal influenza vaccination; OJ L348/71; 29 December 2009

Council Recommendation 2009/C151/01 of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections.

Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia (2004).

Vilnius Declaration on Measures to Strengthen Responses to HIV/AIDS in the EU and in Neighbouring Countries (2004).

Bremen Declaration on responsibility and partnership – Together against HIV/AIDS (2007).

Communication from the Commission COM (2009) 569 on combating HIV/AIDS in the EU and neighbouring countries 2009 – 2013.

Council conclusion on pandemic influenza preparedness planning, 1 June 2004.

Commission Communication on generic preparedness planning of 28.11.2005 COM (2005) 605 final.

EC Strategy for Generic Preparedness Planning – technical guidance of 01 December 2009 (update April 2011).

Council Conclusions on Childhood Immunisation, 6 June 2011.

Communication from the Commission COM (2001) 0333 final of 20 June 2001 on a community strategy against antimicrobial resistance.

The European Community Strategy against Antimicrobial Resistance Eurosurveillance Volume 9, Issue 1, 01 January 2004.

Pandemic Influenza Preparedness and Response Planning Commission information to the Council 30 May 2005.

Community Network For The Epidemiological Surveillance And Control Of Communicable Diseases: Epidemiological Surveillance Component (ESCON) List of Designated authorities

Council Conclusions on AMR (10 June 2008).

Council Conclusions on the impact of antimicrobial resistance in the human health sector and in the veterinary sector – a 'One Health' perspective (22 June 2012).

Commission Implementing Decision 2014/504/EU of 25 July 2014 implementing Decision No 1082/2013/EU of the European Parliament and of the Council with regard to the template for providing the information on preparedness and response planning in relation to serious cross-border threats to health; OJ L 223, 29.7.2014, p. 25-36

Council conclusions on vaccinations as an effective tool in public health (1 December 2014).

Council conclusions on patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance (1 December 2014).

ECDC documents

ECDC Strategic Multi-annual Programme (SMAP) 2014–2020

Framework for a strategy for infectious disease surveillance in Europe (2006–2008) – MB 27-29 October 2005.

ECDC Strategic Multi-Annual Programme 2007–2013

ECDC Health Communication Strategy 2010–2013

ECDC Surveillance of communicable diseases in the EU, A long-term strategy: 2008–2013

The Framework Action Plan to Fight TB in the EU (February 2008)

Progressing towards TB elimination – follow up to the Framework Action Plan to fight Tuberculosis in the EU (2010)

ECDC TD Core competences for field epidemiology in Europe, January 2008

European core curriculum for training for infection control practitioners, March 2013

ECDC Technical Report 'Core functions of microbiology reference laboratories for communicable diseases', June 2010

Web service TESSy:
http://ecdc.europa.eu/en/publications/Publications/1003_TER_TESSy_transport_protocol_XTML.pdf

TESSy_Transport_Protocol_CSV_v2.7

ECDC TED – European Legionnaires' Disease Surveillance Network (ELDSNet): Operating procedures. Stockholm: ECDC; January 2012

EWGLI Technical Guidelines, September 2011

EPIS Vaccine Preventable Diseases Network – procedures, draft 8 September 2011

EPIS AMR – HAI, Terms of Reference of EPIS ARHAI users, draft

EPIS FWD – procedures, draft 18 January 2010

EPIS STI – ECDC Procedures, August 2010

ECDC TED – HAI antimicrobial use protocol_v4.3_May2012

ECDC Coordinating Competent Bodies_7 December 2012

ECDC National Coordinator ToR_7 December 2012

ECDC NFP for Disease Groups_7 December 2012

ECDC NFP for PH functions_7 December 2012

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http://www.eucast.org/clinical_breakpoints/

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http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/AFST/Antifungal_breakpoints_v_6.1.pdf
http://www.eucast.org/clinical_breakpoints/

ECDC roadmap for integration of molecular typing into European level surveillance and epidemic preparedness- under drafting

International documents

WHO International Health Regulations 2005

EC-ECDC-WHO joint European Pandemic Preparedness Self-Assessment Indicators, March 2010

Eliminating measles and rubella, and preventing congenital rubella infections; WHO European Region strategic plan 2005–2010

Framework for Evaluating Public Health Surveillance Systems for Early Detection of Outbreaks (CDC Recommendations of 7 May 2004/ 53(RR05):1-11

WHO–recommended standards for surveillance of selected vaccine-preventable diseases WHO/V&B/03.01

WHO recommended surveillance standards, second edition WHO/CDS/CSR/ISR/99/2/EN

IHR 2005: Core Capacity Framework: Checklist and Indicators for Monitoring Progress in the Development of IHR Core Capacities in States Parties, WHO 2013

Measles and rubella elimination 2015. Package for accelerated action: 2013-2015 (2013)

Regional framework for surveillance and control of invasive mosquito vectors and re-emerging vector-borne diseases 2014–2020, WHO Europe 2013

ISO 17025:2005. General requirements for the competence of testing and calibration laboratories

ISO 15189:2012. Medical laboratories – Requirements for quality and competence.

Other EU acquis communautaire provisions relevant for public health and communicable disease surveillance

Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (Article 2 par. 2)

Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (Article 21 to apply)

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, 9 March 2011

Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work, 18 September 2000

Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms

Regulation 2001/45/EC of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data

Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

Commission Decision 2001/844/EC, ECSC, Euratom of 29 November 2001 amending its internal Rules of Procedure (OJ L 317, 3.12.2001, p. 1.) – Appendix on classified information re. Decision 1082/2013, Art. 4. p.4

Council Decision 2011/292/EU of 31 March 2011 on the security rules for protecting EU classified information (OJ L 141, 27.5.2011, p. 17.)

Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions 'A comprehensive approach on personal data protection in the European Union' 4.11.2010 COM(2010) 609 final

Annex 2. Assessment tool architecture for assessing communicable disease capacity in EU enlargement countries

Assessment tool architecture for assessing communicable disease capacity in EU enlargement countries		
Number	**Heading**	**Rationale[7]**
1	2	3
1. Health governance		
1.1	Legislation	
Framework questions 1, 2 and 3	• Does the country have provisions that allow for the full implementation of the EU acquis with regard to the communicable disease system? • Does the country have the infrastructure in place to implement the EU acquis and related recommendations/best practise in the field of communicable diseases? • Does the country have the administrative capacities – including human resources, technical equipment, and sustainable funding – to implement the EU acquis and related recommendations/best practise in the area of communicable diseases?	
1.1.1	Legislation, regulations and administrative requirements regarding communicable disease surveillance, prevention and control	Regulation 851/2004/ EC, Art. 30.1.
1.1.2	List of diseases to be reported	Decision 2000/96/EC + amendments (consolidated text)
1.1.3	Case definitions	Decision 2002/253/EC + amendment: Decision 2012/506/EU
1.1.4	Personal data protection	Directive 95/46/EC; Regulation 45/2001/EC Decision 2000/57/EC + amendments (consolidated text), Art. 2a (2).
1.1.5	Plans for developing or amending national legislation	Enlargement process, stabilisation and association agreements
1.1.6	Communication of epidemiological data with ECDC	Regulation 851/2004/ EC, Art. 4
1.2	Organisational structures/institutional and financial sustainability of the system	
Framework question 3	Does the country have the administrative capacities – including human resources, technical equipment, and sustainable funding – to implement the EU acquis and related recommendations/best practise in the area of communicable diseases?	
1.2.1	Description of the overall organisation of health and public health services related to communicable disease prevention and control	Regulation 851/2004/ EC, Art. 9.6
1.2.2	Financial and institutional sustainability of the system, access to health services.	
1.2.3	Competent authorities and institutions	Decision 1082/2013/EU Decision 2000/57/EC + amendments (consolidated text)
1.3	Future participation of the country in EU structures	
13a	Community Network of Decision 1082/2013/EU	Decision 1082/2013/EU, Art. 6
13b	EWRS Focal Point	Decision 1082/2013/EU, Art. 6, Art. 8 and Decision 2000/57/EC + amendments (consolidated text)
13c	Health Security Committee	Decision 1082/2013/EU, Art. 17
13d	ECDC mechanism and structures for relations with countries	Regulation 851/2004/ EC, Art. 2 (a)
2. Human resource capacity development		

[7] Rationale: reference to EU legislation, EU or non-EU gudelines, setting standards or requirements for the particular area or element

Assessment tool architecture for assessing communicable disease capacity in EU enlargement countries		
Number	**Heading**	**Rationale[7]**
1	2	3
Framework question 3	Does the country have the administrative capacities including human resources, technical equipment, and sustainable funding – to implement the EU acquis and related recommendations/best practise in the area of communicable diseases?	
2.1	Capacity in applied/field epidemiology	Regulation 851/2004/ EC, Art 9.6
2.1.1	Workforce planning	
2.1.2	Specialist workforce related to communicable disease prevention and control	
2.2	Training and education	Regulation 851/2004/ EC, Art 9.6
2.2.1	Areas of specialisation related to communicable disease prevention and control	
2.2.2	Master in public health programmes	
2.3	Curricula for specialisation or post-graduate training in applied epidemiology, public health microbiology and related specialties	List of 80 core competences for field epidemiology in Europe; Scientific guide of the European public health microbiology training programme
2.4	Continuing professional development (communicable disease surveillance and response functions)	
2.4.1	Public Health staff responsible for communicable disease surveillance, public health microbiology, outbreak investigation	ECDC TD Core competences for field epidemiology in Europe, January 2008
2.4.2	Clinical staff responsible for reporting communicable diseases and/or infection control	Core competencies for infection control and hospital hygiene professionals in the European Union, March 2013
2.5	Licensing of public health workforce	
3. Surveillance		
Framework question 4	Does the surveillance of communicable diseases meet EU standards with regard to epidemiologic data on all diseases under EU surveillance, their case definitions and reporting protocols?	
3.1	National surveillance system description	
3.1.1	System objectives	International guidelines: CDC 2001 WHO 2006: Good practice in Member States. Objectives for strengthening the surveillance of communicable diseases in the European Union. ECDC long-term surveillance strategy: 2008–2013, p.10-13
3.1.2	System overview	WHO recommended surveillance standards, Second edition WHO/CDS/CSR/ISR/99/2/EN WHO–recommended standards for surveillance of selected vaccine-preventable diseases WHO/V&B/03.01
312b	Diseases under surveillance	Commission Decision 2009/312/EC of 2 April 2009 amending Decision 2000/96/EC as regards dedicated surveillance networks for communicable diseases, OJ L 91/27; 03 April 2009 Decision 2000/96/EC + amendments (consolidated text)
312c	24/7 system for reporting	Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under

Assessment tool architecture for assessing communicable disease capacity in EU enlargement countries		
Number	**Heading**	**Rationale[7]**
1	2	3
		Decision No 2119/98/EC of the European Parliament and of the Council. OJ L 21/32; 26 January 2000 + amendments (consolidated text) Commission Decision 2008/351/EC of 28 April 2008 amending Decision 2000/57/EC as regards events to be reported within the early warning and response system for the prevention and control of communicable diseases OJ L 117/40; 01.05.2008
312d	Cases reported to public health authorities	Decision 1082/2013/EU; WHO International Health Regulations 2005
312e	Reporting source(s)	Decision 1082/2013/EU; WHO International Health Regulations 2005
312f	Case confirmation (processes)	Decision 1082/2013/EU; WHO International Health Regulations 2005
312g	Classification of notified disease	Commission Implementing Decision 2012/506/EU of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council
312h	Reporting flows (system chart)	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.1.3	Databases and information technology	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.1.4	Data analysis	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.1.5	Reporting and feedback of communicable disease surveillance information	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.1.6.1	(1) Additional major disease-specific surveillance systems	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.1.6.2	(2) Additional major disease-specific surveillance systems	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.1.7	Sentinel surveillance systems	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.1.8	Syndromic surveillance systems	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.1.9	Personal data protection	Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions A comprehensive approach on personal data protection in the European Union
3.2	Surveillance system assessment	
3.2.1	Evaluation and monitoring of surveillance systems	International guidelines: CDC 2001 WHO 2006: Good practice in Member States (applies to Section 3.2). Framework for evaluating public health surveillance systems for early detection of outbreaks

Assessment tool architecture for assessing communicable disease capacity in EU enlargement countries		
Number	**Heading**	**Rationale[7]**
1	2	3
3.2.2	Sensitivity and validity of surveillance system data (external completeness)	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.2.3	Internal completeness and validity of surveillance system data	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.2.4	Timeliness of surveillance system data	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.3	System coordination and integration	
3.3.1	Coordination and integration of national reporting systems	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.3.2	National reporting, case-based surveillance data	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.3.3	International reporting, case-based data	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.3.4	Reporting of individual case data to TESSy	Regulation 851/2004/ EC, Art. 4, Art. 30; Decision 1082/2013/EU; ECDC TESSy ToR (CC/PCC nominations)
3.4	Outbreak detection and control	
3.4.1	Outbreak definition and reporting	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.4.2	Outbreak control	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.5	Response to national and high-risk outbreaks of communicable diseases	
3.5.1	Mechanism for the mobilisation of emergency response teams	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.5.2	Central epidemic management committee	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.5.3	Participation in international outbreak response activities	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.6	Epidemic intelligence	
3.6.1	Information sources and tools for detection of communicable disease alerts/ public health events	Decision 1082/2013/EU; WHO International Health Regulations 2005
3.6.2	Validation of detected events	Decision 1082/2013/EU; WHO International Health Regulations 2005
4. Public health emergencies: preparedness and response		
Framework question 5	Does the preparedness and response system in the area of public health emergencies (including communicable diseases) meet the EU standards in preparedness, and is there sufficient institutional capacity to timely provide comparable data and participate in coordinated activities organised by ECDC and other EU bodies?	
4.1	Management of preparedness plans	Decision 1082/2013/EU; WHO International Health Regulations 2005
4.1.1	Parties involved, responsibilities, cross-sectoral collaboration	Implementing Decision 2014/504/EU
4.2	Coordination structures for cross-sectoral incidents	Decision 1082/2013/EU; WHO International Health Regulations 2005 Implementing Decision 2014/504/EU
4.3	Strategic and operational coordination of serious cross-border threats to health	Decision 1082/2013/EU; WHO International Health Regulations 2005 Implementing Decision 2014/504/EU
4.4	Business continuity planning associated with serious cross-border threats to health	Decision 1082/2013/EU; WHO International Health Regulations 2005 Implementing Decision 2014/504/EU
4.5	Capacity to anticipate, respond to, and recover from, the impact of likely, imminent or current public health crises	Decision 1082/2013/EU; WHO International Health Regulations 2005 Implementing Decision 2014/504/EU
4.5.1	National plan for epidemic preparedness and response	Commission Communication on generic preparedness planning of 28.11.2005 COM(2005) 605 final

Assessment tool architecture for assessing communicable disease capacity in EU enlargement countries		
Number	**Heading**	**Rationale[7]**
1	2	3
4.5.2	Joint procurement of medical countermeasures	Decision 1082/2013/EU
4.6	International reporting	
4.6.1	Early Warning and Response System (EWRS)	Decision 1082/2013/EU Decision 2000/57/EC + amendments (consolidated text) Decision 2009/547/EC; Regulation 851/2004/EC, Art. 4, 8, 10.1
461a	24/7 structure for response	
461b	EWRS focal points	
461c	EWRS criteria for reporting at EU level	
4.6.2	Epidemic Intelligence Information System (EPIS)	Regulation 851/2004/ EC, Art. 4, Art. 30 Decision 1082/2013/EU ECDC TESSy ToR (CC/PCC nominations)
4.6.3	International Health Regulations (IHR)	International Health Regulations 2005 Decision 1082/2013/EU Implementing Decision 2014/504/EU
4.7	Risk communication	
4.7.1	Communication infrastructure for emergency communication	EC Strategy for Generic Preparedness Planning. Technical guidance on generic preparedness planning for public health emergencies, EC 2009 (update April 2011). WHO International Health Regulations 2005
4.7.2	Communication: public health planning, public health advice for political decision-makers, and cross-sectoral issues	Regulation 851/2004/ EC, Art. 12 (2). ECDC Health Communication Strategy 2010-2013 (p. 2, 3, 4, 6)
4.7.3	Coordination and consistency of communication efforts	ECDC Surveillance of communicable diseases in the EU, A long-term strategy: 2008-2013 (p 8).
5. National system of public health microbiology laboratories		
Framework questions 1, 3 and 4.	• Does the country have provisions that allow for the full implementation of the EU acquis with regard to the communicable disease system? • Does the country have the administrative capacities – including human resources, technical equipment, and sustainable funding – to implement the EU acquis and related recommendations/best practise in the area of communicable diseases? • Does the surveillance of communicable diseases meet EU standards with regard to epidemiologic data on all diseases under EU surveillance, their case definitions and reporting protocols?	
5.1	Description of the microbiology laboratory system for public health	
5.1.1	Legal basis and system structure	IHR Core Capacity Monitoring Framework/WHA indicators (Indicator 1)
5.1.2	Organisational structure	ECDC Technical Report 'Core functions of microbiology reference laboratories for communicable diseases'
5.1.3	Coordination of microbiology services	Decision 1082/2013/EU
5.2	Primary microbiology laboratory services	
5.2.1	Diagnostic microbiology testing	ECDC Technical Report 'Core functions of microbiology reference laboratories for communicable diseases'
5.2.2	Molecular typing	ECDC SMAP 2014-2020 ECDC Roadmap for integration of molecular typing into European level surveillance and epidemic preparedness
5.2.3	National surveillance networks of sentinel laboratories	Decision 1082/2013/EU ECDC Technical Report 'Core functions of microbiology reference laboratories for communicable diseases'

Assessment tool architecture for assessing communicable disease capacity in EU enlargement countries		
Number	**Heading**	**Rationale[7]**
1	2	3
5.3	Reference microbiology laboratory services	
5.3.1	Terms of reference	ECDC Technical Report 'Core functions of microbiology reference laboratories for communicable diseases'
5.3.2	Functions of reference microbiology laboratories	ECDC Technical Report 'Core functions of microbiology reference laboratories for communicable diseases'
5.3.3	External quality assessment schemes	ECDC Technical Report 'Core functions of microbiology reference laboratories for communicable diseases' ISO 17025:2005 General requirements for the competence of testing and calibration laboratories ISO 15189:2012. Medical laboratories – Requirements for quality and competence
5.4	Laboratory biosafety regulation, certification and auditing	Directive 2000/54/EC Directive 2009/41/EC IHR Core Capacity Monitoring Framework/WHA indicators (Indicator 13) ISO 17025:2005 General requirements for the competence of testing and calibration laboratories ISO 15189:2012. Medical laboratories – Requirements for quality and competence
5.5	Microbiology laboratory support during outbreaks	ECDC Technical Report 'Core functions of microbiology reference laboratories for communicable diseases' IHR Core Capacity Monitoring Framework/WHA indicators (Indicators 13, 17, 18)
5.6	Business continuity for public health microbiology services	Decision 1082/2013/EU
6. Disease programmes		
Framework question 4:	Does the surveillance of communicable diseases meet EU standards with regard to epidemiologic data on all diseases under EU surveillance, their case definitions and reporting protocols?	
6.1	Antimicrobial resistance and healthcare-associated infections	
6.1.1	Antimicrobial resistance	Council Recommendation 2002/77/EC (prudent use of antimicrobial agents in human medicine); Council Conclusions on AMR (10 June 2008); Council Conclusions on the impact of antimicrobial resistance in the human health sector and in the veterinary sector – a 'One Health' perspective (22 June 2012) Council conclusions on patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance (1 December 2014)
6.1.2	Healthcare-associated infections	Council Recommendation 2009/151C/01 (patient safety, including the prevention and control of healthcare associated infections) Council conclusions on patient safety and quality of care, including the prevention and control of healthcare associated infections

Assessment tool architecture for assessing communicable disease capacity in EU enlargement countries		
Number	**Heading**	**Rationale[7]**
1	2	3
		and antimicrobial resistance (1 December 2014)
6.2	Programme on HIV, STI and blood-borne infections	Dublin Declaration and Vilnius Declaration on HIV/AIDS Commission Directives on blood, cells and tissues and organs
6.3	Tuberculosis	The Framework Action Plan to Fight TB in the EU (2008) and Progressing towards TB elimination (2010)
6.4	Influenza	Council Recommendation 2009/1019/EC of 22 December 2009 on seasonal influenza vaccination Council conclusion on pandemic influenza preparedness planning 1 June 2004; Commission Communication on generic preparedness planning of 28.11.2005 COM(2005) 605 final EC-ECDC-WHO joint European Pandemic Preparedness Self-Assessment Indicators, March 2010
6.5	Food- and waterborne diseases and zoonoses	EU Directive for the Protection against Specified Zoonoses and Specified Zoonotic Agents in Animals and Products of Animal Origin Category, 92/117/EC and Zoonoses Monitoring Directive 2003/99/EC; Community legislation on TSEs
6.6	Emerging and vector-borne diseases	Regional framework for surveillance and control of invasive mosquito vectors and re-emerging vector-borne diseases 2014–2020.
6.7	Vaccine-preventable diseases and invasive bacterial infections	Eliminating measles and rubella, and preventing congenital rubella infections; WHO European Region strategic plan. Council Conclusions on Childhood Immunisation Council conclusions on vaccinations as an effective tool in public health (1 December 2014) Measles and rubella elimination 2015. Package for accelerated action: 2013-2015 (2013)

Annex 3. Methodologies for data collection, data analysis, and preliminary report writing

3.1 Scope and introduction

This document is to guide the assessment team in collecting, validating and analysing the information collected at various steps of the assessment process. It is also intended to assist the team in preparing and developing a comprehensive assessment report. The methodology outlined here should be followed when processing data from the different assessment areas (Annex 2) in order to ensure a consistent and effective approach with regard to the framework questions formulated in this technical document.

All assessment tools were developed in line with the documents listed in Annex 2. The 'assessment tool architecture' in Annex 2 served as the basis for the list of assessment questions (Table A in supporting document 3.1[8]) which explore the capacity in communicable disease prevention and control). Some of these questions are included in the self-assessment questionnaire (Annex 4); other questions will be posed during the assessment mission in the enlargement country. These questions, together with additional requests for clarification, constitute a separate field assessment questionnaire (Table B in supporting document 3.2).

The assessment team can use the guidelines in supporting document 3.3 (see end of Annex 3, *List of supporting documents*) to identify the sites to be visited. Supporting document 3.4 provides a description of, and templates for, a SWOT analysis to be performed during the mission. These tools should facilitate the collection and analysis of information collected in the enlargement country.

3.2 Working methods of the assessment team

The team will:

- collect and review information, record answers to assessment questions, and analyse additional documents provided by the country;
- validate collected information during the field assessment through site visits, semi-structured interviews, examination of documentation, and exploration of 'system test cases';
- conduct site visits and gain insights from reality-check tests/mock-up exercises;
- evaluate and synthesise the collected information, including information on the function and the various aspects of the communicable disease system;
- develop recommendations; and
- present conclusions.

3.3 Assessment process

The assessment process will be performed with the following steps (numbers refer to the subsections below):

- 4.1. Review of existing information in preparation for the assessment process
- 4.2. Review of responses to self-assessment questionnaire; requests for additional documents, information and clarification
- 4.3. Assessment team provisional analysis of conclusions; proposed questions/areas to be addressed during the country visit, including cross-cutting issues
- 4.4. Preparation for the field assessment; itinerary for proposed sites
- 4.5. Analysis of information during the assessment visit
- 4.6. System domain analysis, conclusions, individual analysis and recommendations
- 4.7. Assessment team joint analysis: conclusions and proposed recommendations.

[8] Supporting documents are not included in this publication and are only available to the assessment team.

Review of existing information in preparation for the assessment process

- Information sources – Documents produced by ECDC, the European Commission, WHO; publications available download
- from official websites of country institutions, epidemiological reports, scientific articles, conference presentations, and other relevant sources
- Analysis – Does the background information already answer any aspects addressed in the self-assessment questionnaire? Based on the collected information, can you identify specific, additional areas to be addressed during the assessment? Should these be addressed before or during the country visit?
- Action – Record all conclusions or observations of importance (column 3 in Table A in supporting document 3.1). This information is essential to prepare for the country visit.

Table A. Excerpt from assessment table on country capacity in communicable disease prevention and control with pre-assessment research conclusions

List of assessment questions on country capacity in communicable disease prevention and control				
No	Self-assessment questions	A. Requests for clarification and additional documents before the visit B. Suggested field assessment questions	Criteria: Necessary Advisable Optional Cross check	Observations
1	2	3	4	5
	5.1.1. Antimicrobial resistance			
1.	611a. Does your country have a national strategy and/or action plan on the prudent use of antimicrobial agents in human medicine and veterinary medicine?	A. … B. …		
2.	611b. If yes, does it identify sources of funding of specific activities of the plan/strategy?			
3.	611c. Does your country have an intersectoral coordination mechanism for the implementation of the plan/strategy?			

Review of responses to self-assessment questionnaire; requests for additional documents, information and clarification

- Information sources – supporting document 3.1, Table A, completed with information collected by the assessment team as described above. Responses to self-assessment questionnaire. Additional documents accompanying the responses.
- Analysis – Do information collected together with responses to self-assessment questionnaire and accompanying documents fully address aspects of the national CD system which the questions aimed at assessing? Is the information consistent? What contradictions or inconsistencies can be identified? What additional information, data, documents or clarifications should be requested and from whom?
- Action – Formulate request for additional information, data, documents or clarification. Please note that requests for clarification and additional documents should be compiled together and send by the team leader.

Assessment team provisional analysis of conclusions, proposed questions/areas to be addressed during the country visit, including cross-cutting issues

- Information sources – Documents produced by ECDC, the European Commission, WHO; publications at official websites of country institutions, epidemiological reports and scientific articles, presentations during conferences, and other relevant sources; responses to self-assessment questionnaire and additional clarifications with accompanying documents;
- Analysis – Do you have sufficient information to identify strengths and weaknesses of the country system, drawing conclusions and relevant recommendations? Are there still uncertainties as regards the consistency of information? Which areas/aspects require validation during the field assessment? What would the appropriate questions be and who should be the addressee of these questions to validate the information? Which cross-cutting issues should be addressed in more detailed during the country visit?

- Action – using the template provided in Table B in supporting document 3.2. prepare draft field assessment questions and instructions for the field assessment completing column 3 and 4 of the table. Draft scenarios for mock-up exercises or reality check tests.

Table B. Excerpt from assessment table and instructions for country mission

Preparations for the field assessment				
Analysis of answers to self-assessment questions				
Serial number	Systematic number	A. Is the answer complete? B. Can you draw conclusions? C. Additional info, data, document needed? D. Do you need to validate information in the field and how you will do this?	A. Requests for clarification and additional documents B. Field assessment questions C. Sites to be visited D. Addressee of the field questions E. Reality-check tests	A. Answers obtained in the field B. Observations C. Comments
1	2	3	4	5
	4.4.3. Epidemic Intelligence Information System (EPIS)			
	4431a			
	4431b			
			4432a. Please describe the last event posted on the EPIS platform.	

Preparation for the field assessment, itinerary for proposed sites

- Information sources – Analysis performed above (point 4.1; 4.2; and 4.3) Responses to self-assessment questionnaire, documents accompanying the responses, records of requests for clarification/corrections, information collected in response to the analysis of information which indicates uncertainties, inconsistencies and/or incomplete answers, etc.
- Analysis – Which sites should be visited in order to properly address the assessment areas? Are there any cross-cutting areas and/or cross-checking questions?
- Action – Identify institutions and persons to be reviewed during the country assessment. Identify regional structures. Identify sites to be visited. Criteria for the site selection: population covered by disease surveillance, epidemiological characteristics of the region, and possible risk of outbreaks, including the level of cross-border migration. Follow the guidelines outlined in Annex 3.3. Draft the programme and terms of reference of the assessment mission.

Analysis of information during the assessment visit

- Information sources – Data collected during site visits with the field-assessment questionnaire and reality-check tests, observations made during the country visit, documents collected during the visit.
- Analysis – Compiling all relevant information from the sources above. Does this information properly addresses the areas/issues outlined in the preparation of the country visit? Is the information sufficient to draw conclusions on the current situation of all assessment areas and topics? Consider also acid-test questions and reality-check questions: did they fulfil their purpose, is the information consistent and sufficient? If anything is missing, please consider possible requests for clarification.
- Action – After each day of the assessment visit, preliminary conclusions should be written down; populate column 5 of Table B in supporting document 3.2.

System domain analysis, conclusions, individual analysis and recommendations

- Information sources – Results of all performed analyses (see above), notes from columns 3 and 5 of Table B in supporting document 3.2, other documents or individual notes of assessment team experts.
- Analysis – Individual conclusions for all assessment areas (areas of responsibility), individual analysis: strengths and weaknesses of the system.
- Action – Draft the individual intermediate report with your conclusions, identified strengths and weaknesses and suggested recommendations.

Assessment team joint analysis: conclusions and proposed recommendations

- Information sources – Conclusions, strengths and weaknesses as previously identified, recommendations proposed by the members of the assessment team.
- Analysis – Joint review of conclusions, strengths, weaknesses, and recommendations. Discussion of opportunities and threats along each area of assessment. Discuss results with team to ensure consistency, follow through on cross-cutting issues, explain the conclusions, and reach a common agreement on what should be included in the draft report.

- Action – Discuss and draft final comments, conclusions and recommendations. Clearly describe the identified strengths and weaknesses. When considered necessary by the assessment team – provided that sufficient data have been collected – you may proceed with a SWOT analysis (see guidance and the template in Annex 3.4).
- Distribution of tasks: draft the technical assessment report (see Annex 6).

3.4 Recommendations and reporting

All recommendations and proposals for improvement should be based on:

- an analysis of the pre-assessment materials;
- an analysis of the information gathered during the field visits, i.e. is the insights obtained during the interviews and the answers in the questionnaires;
- strengths, weaknesses, opportunities and threats identified in the SWOT analysis;
- prioritisation of solutions, opportunities, threats to the country accession process;
- recommendations to strengthen the capacity, improve coordination, build synergies, and take advantage of the driving forces of the national communicable disease system.

The technical assessment report should follow the standard format as proposed in Annex 6.

3.5 List of supporting documents

In addition to the information supplied in Annex 3 of this technical document, the following supporting documents are supplied to the assessment team:

Supporting document 3.1 (Table A). List of assessment questions on country capacity in communicable disease prevention and control

Supporting document 3.2 (Table B). Field assessment questions and instructions for country mission

Supporting document 3.3. Identification and assessment of sites at the rural/provincial level of EU enlargement countries

Supporting document 3.4. Strengths, weaknesses, opportunities and threats: SWOT analysis of the EU enlargement country

Supporting document 3.5. Template of the mock-up/reality-check/exercise scenario

Annex 4. Self-assessment questionnaire for enlargement countries

Questionnaire

Due to its size, the questionnaire is not included in this document. It is available as a separate download from http://ecdc.europa.eu/en/aboutus/Partnerships/Pages/Assessment-of-enlargement-countries.aspx.

Instructions for questionnaire

The instructions are part of the separate questionnaire mentioned above.

Annex 5. Assessment of country missions: practical guidelines

Scope

This document provides the assessment team with template documents and guidance for preparing and conducting assessment country missions.

5.1 Terms of reference for the assessment team

Technical note: This is an internal document providing guidance regarding the composition of the team, explaining its tasks, its role, and its relations with ECDC and other stakeholders involved in the assessment process.

5.2 Template: terms of reference for the assessment mission

Assessment mission to [country name]

Assessment of country capacities in communicable disease surveillance, prevention and control

Mission date: [00 Month 2099]

Background

On [00 Month 2099], the European Commission invited [country] to accept an assessment mission[9] to review the communicable disease prevention and control system ('the system'). Following the consent of the Minister of Health[10], the European Commission, ECDC and their partners in the country agreed to conduct the assessment mission between [00 Month 2099] and [00 Month 2099]. Contact persons in the European Commission, the European Centre for Disease Prevention and Control, the Ministry of Health, and the Public Health Institutions of [country] agreed upon the technical arrangements to perform the assessment. These arrangements are described herein as terms of reference for the mission.

Objectives of the assessment mission

The objectives of the mission are:

- to review the implementation of EU communicable disease legislation[11];
- to review the administrative and institutional capacity available to implement EU legislation;
- to verify the sustainability of communicable disease prevention and control in the enlargement country. This information should complement the answers of the self-assessment questionnaire;
- to learn about the country's best practices and assess the progress in applying EU best practices;
- to better understand the strengths and achievements of the country in the areas of health governance, capacity development, surveillance, preparedness and response, public health microbiology laboratories, and disease programmes, as well as sustainability of the system;
- to meet national experts at all levels (i.e. primary, regional, national level) in order to better understand their activities and learn their views on strengths and weaknesses of the national communicable disease system;
- to identify areas for possible improvement and suggest solutions to help strengthening the national communicable disease system;
- to provide practical information on how the communicable disease system of the EU enlargement country functions; and
- to exchange information that will facilitate the country's participation in ECDC activities.

In addition to these objectives, this visit will be used to [please specify].

[9] Letter of the Directorate General for Health and Food Safety to Mr/Ms … (Ministry of Health), dated [00 Month 2099]

[10] Letter by Mr/Ms … (Ministry of Health) to the Directorate General for Health and Food Safety dated [00 Month 2099]

[11] Legislative alignment will be checked in advance by the European Commission.

Assessment scope

The areas to be assessed are: health governance (Section 1 of the self-assessment questionnaire), sustainability of the system and capacity development (Section 2), surveillance (Section 3), preparedness and response (Section 4), public health microbiology laboratories (Section 5), and disease programmes (Section 6).

The assessment visit will be preceded by a pre-assessment seminar organised in Stockholm which will review the answers to the self-assessment questionnaire, which are provided by the country before the assessment mission. The assessment mission will mainly focus on the evaluation of the previously collected information.

Methodology

The team will use the following working methods:

- Collecting and reviewing existing information, including answers to assessment questions and documents provided by the country.
- Validating information collected during field assessments, e.g. in seminar discussions, working groups, interviews; cross-cutting issues from different assessment areas will be considered.
- Collecting observations during site visits and from reality-check tests.
- Analysing collected information and synthesising conclusions and recommendations.

Specific arrangements in the country

Language

The language of the assessment is English. Country officials and experts involved in the assessment should be able to communicate in English. Country authorities should provide interpreters for all groups working in the field and for the plenary meetings.

Logistics

Host institutions will be responsible for appropriate meeting venues; they will also provide equipment and secretarial services. Details will be arranged before the mission.

Transportation and accommodation

Host institutions will assist the assessment team in arranging transportation within the country and provide accommodation outside the capital, if needed. During visits in provinces, the EU experts will be accompanied by local partners and representatives of competent central institutions.

Expected deliverables

Within three months after the assessment mission, a draft technical assessment report will be produced based on the information from the self-assessment questionnaire and the assessment mission. After consultations with the assessed enlargement country, a draft version of the technical assessment report will be submitted to the Commission for analysis. This draft report will not be published. The Commission will prepare a final assessment report on the country's communicable disease prevention and control system to the Ministry of Health and will invite the country to develop an action plan which addresses the report's recommendations.

Team composition and assignments of team members and country counterparts

Table 1. Team composition

Members of ECDC assessment team				Country experts providing operational support during the visit			
No.	Name	Institution	Initials	No.	Name	Institution	Initials
European Commission officials				**Other institutions**			
No.	Name	Institution	Initials	No.	Name	Institution	Initials

Table 2. Assessment team, by area

	Assignment of assessment areas	Lead[12]	Support[13]	National counterpart
1	Health governance (Section 1)			
2	Sustainability of the system (Section 1.2.2)			
3	Capacity development, education and training (Section 2)			
4	Surveillance (Section 3)			
5	Preparedness and response (Section 4)			
6	IT/TESSy surveillance (Sections 3.1.3, 3.3.4 and 3.3.5)			
7	Public health microbiology laboratories (Section 5)			
8	Disease programmes (Section 6)			
9	Country cooperation and logistics			

Table 3. Destinations of field groups

	Destinations of the field group		ECDC assessment team		Country counterparts	
	Region	District	Lead	Member	National	Local
1						
2						
3						
4						
5						
6						

During the visit, the technical assessment team will be accompanied by EU officials, pending on availability. Representatives of WHO may participate, as appropriate. Back-office support will be provided by ECDC staff in Stockholm.

Programme

The assessment mission will last one to two weeks. During the first few days of the mission, field assessment groups will visit sites at the subnational level[14]. All sites will be determined together with the national counterparts. Each field assessment group will be composed of two assessment team members, one ECDC staff member, and one external expert.

After completing their tasks in the provinces, the field assessment groups will return to the capital in order to consolidate the collected information and report to the team leader. Some assessment team members will then return home, while others will continue the assessment at the national level.

At the end of the assessment mission, the assessment team will analyse the collected information and draft preliminary conclusions, which will be discussed with national leaders and experts during the debriefing session that marks the end of the mission.

Field assessment at the subnational level

The aim of this field assessment is to understand the operation of several systems at the subnational level, namely the systems for disease surveillance, early detection, preparedness and response, and laboratory analysis. Assessors follow the identification of communicable disease cases from the source to the point at which the disease data are transmitted to the national level. It is also important to understand the role of the province health authorities in this context.

1) Introductory plenary with regional public health units, laboratories, and representatives of other stakeholders:

- Introduction and overview regarding scope and purpose of visit
- Introductory presentations by province and district leaders, covering the structure and organisation of the systems under assessment; infrastructure overview, public health capacity, workforce education and training, followed by brief discussion.

[12] Lead – Responsibilities include: planning detailed visit implementation, including instruments and procedures; draft the assessment country report; supporting the production of the report; finalizing the overall conclusions; contributing to analyses; and validating the assessment tools and process.

[13] Support – Support members support the lead member in the assessment process, help with follow-up analyses. The support team member does not participate in the assessment visit.

[14] The number of regions and field groups has to be decided in accordance with the size of the country and the organisational structures.

2) Visits and interviews; the team will meet lead members of public health staff at relevant organisations at the regional, district, and municipality levels:

- Primary medical care facilities
- First contact point for the patient: a health practitioner who is able to make a provisional diagnosis, arrange for confirmatory tests for common notifiable diseases, and is responsible for notifying disease on suspicion
- Regional, district or municipal hospitals, infectious disease wards or units
- First entry point for the patient into the hospital system for diagnosis/care of communicable diseases requiring hospital facilities; infectious disease physicians, the specialists responsible for healthcare-associated infections, and the physicians who manage cases of TB and HIV at this level
- Regional, district or municipal hospital diagnostic laboratory
- Laboratory which provides infectious disease physicians (see above) with initial diagnostic services for the primary diagnosis of common communicable diseases of public health importance
- District or municipal public health unit (epidemiology and/or statistics and data processing)
- Basic local level of epidemiology services and first point of entry into the system for reporting suspected or confirmed notifiable diseases
- Regional public health units (epidemiology and/or statistics and data processing); regional level of the epidemiology service
- Regional, district or municipal representatives of other agencies at the local level involved in the control of communicable disease outbreaks, e.g. food/ veterinary services, environmental health services, health inspectorate (or equivalent).

National-level assessment

During week two of the assessment mission, the team will focus on the organisation and function of the systems at the national level. This includes the regulatory and coordination functions of the national institutions as well as questions regarding the compatibility of national systems with EU systems.

National-level enquiries

- The assessment visit will start with an introductory plenary attended by representatives of the Ministry of Health, public health institutions[15], representatives of national reference laboratories, and stakeholders from other organisations which will be visited during the course of the mission.
  Presentations by national leaders should cover the essential structure and organisation of the systems under assessment; other topics should include an overview of infrastructure, public health capacity and workforce education and training, surveillance and early detection, preparedness and response systems, and laboratory infrastructure, followed by a brief discussion.
- Detailed technical presentations and discussions with public health institutions and national reference laboratories should be held in parallel groups. Topics to be covered: the organisation and function of surveillance, early detection and response systems, and laboratory systems.

National-level stakeholders

The aim of this component is to understand the roles and organisation of other national-level stakeholders involved in communicable disease surveillance and/or response systems as well as important elements of related infrastructure elements, e.g. epidemiology training and training for other health/laboratory staff.

This component includes meetings with leaders of national key organisations/departments, including those responsible for:

- public health emergency preparedness and response;
- operational aspects of activities supporting the control of communicable disease outbreaks, e.g.
  - environmental health
  - health inspectorate
  - food safety
  - veterinary health;
- professional licensing, planning and implementation of education and training activities, such as continuing professional education of epidemiologists and other key health staff involved in disease surveillance and early detection systems (medical schools/universities, associations of medical professionals).

Technical review meeting

During this meeting with colleagues from national public health institutes and laboratories, the team reviews and verifies their provisional understanding of the structure and functioning of the country's surveillance and early

[15] Should include representatives of the TB and HIV surveillance systems

detection systems in order to clarify technical matters, fill in gaps, and request further information and data as necessary.

Assessment team internal meeting

In this meeting, the assessment team will summarise their provisional key findings.

Debrief meeting

During the debriefing, the assessment team gives feedback to the relevant national authorities and stakeholders. This includes provisional key findings with regard to the strengths and perceived opportunities for the development of the country's communicable disease surveillance and response systems and supporting infrastructure.

Follow-up

The assessment team's recommendations could be used by:

- the enlargement country to create an action plan for improving the communicable disease system, the implementation of legislation and the increase of administrative capacity;
- the Commission to identify potential follow-up actions and projects to support the strengthening of the communicable disease surveillance and response systems in the country, e.g. through training;
- ECDC to plan joint actions strengthening the country's administrative, institutional, and prevention and control capacities, through an agreement between the Directorate-General for Neighbourhood and Enlargement Negotiations (DG NEAR) and ECDC under the Instrument for Pre-accession Assistance (IPA).

Confidentiality and media issues

Access to ECDC documents follows European Union rules and, in particular, Regulation (EC) 1049/2001 and Directive (EC) 291/2006 and the relevant implementing rules concerning the obligation of transparency.

The level of confidentiality as well as the plan for diffusion of the information produced or shared during the visit must be discussed and agreed by the enlargement country, ECDC and the European Commission (DG SANTE).

The final report will be shared with the Public Health Directorate of the European Commission, as the party requesting ECDC to conduct the assessment. The report can be published subject to the agreement of the country and the European Commission.

Presence of the media at meetings during the visit or press releases are not foreseen. No media announcements, notes or press releases covering the event are expected.

For more information, please contact:

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5.3 Template/tables: terms of reference for the assessment mission

Assessment mission to [country name]

Assessment of country capacities in communicable disease surveillance, prevention and control

Date: [00 Month 2099]

Table 4. Name list of participants

Members of ECDC assessment team				Country experts providing operational support during the visit			
No	Name	Institution	Initials	No	Name	Institution	Initials
1				1			
2				2			
3				3			
4				4			
5				5			
6				6			
7				7			
8				8			
9				9			
10				10			
11				11			
12				12			
European Commission officials				**Other institutions**			
No	Name	Institution	Initials	No	Name	Institution	Initials
1				1			
2				2			
3				3			

Table 5. Assessment team members and their tasks

	Assessment team for country assessment visit			
	Assignment of assessment areas	Lead[16]	Support[17]	National counterpart
1	Health governance (Section 1)			
2	Sustainability of the system (Section 1.2.2)			
3	Capacity development, education and training (Section 2)			
4	Surveillance (Section 3)			
5	Preparedness and response (Section 4)			
6	IT/TESSy surveillance (Sections 3.1.3, 3.3.4 and 3.3.5)			
7	Public health microbiology laboratories (Section 5)			
8	Disease programmes (Section 6)			
9	Country cooperation and logistics			

Table 6. Assessment in the field: regions and responsible team members

[16] Lead – lead team member's responsibilities include: planning detailed visit implementation, including instruments and procedures; ensure correct understanding of the information collected on site; draft the respective text for the assessment country report; support compiling the report and finalizing the overall conclusions, and contribute to analysis of the test and validation of the assessment process and tools.

[17] Support – support team member's responsibility is to support the respective lead in the assessment process and follow up analysis (on-site meetings, report writing); the support does not participate in the assessment visit.

	Field groups' destinations		ECDC assessment team		Country counterparts	
	Region	District	Lead	Member	National	Local
1						
2						
3						
4						
5						
6						

Table 7. Travel itinerary[18]

Detailed plan of the assessment visit								
		Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	Assessment team member	Region						
GROUP 1/R1	ECDC	Travel to Stockholm	Capital/travel	Travel to R1	R1	Capital	Summary	Travel to Stockholm
	External experts	Travel	Capital/travel	Travel to R1	R1	Capital	Summary	Travel
	EC/WHO/other	Travel	Capital/travel	Travel to R1	R1	Capital	Summary	Travel
GROUP 2/R2	ECDC	Travel to Stockholm	Capital/travel	Travel to R2	R2	Capital	Summary	Travel
	External experts	Travel	Capital/travel	Travel to R2	R2	Capital	Summary	Travel
	EC/WHO/other	Travel	Capital/travel	Travel to R2	R2	Capital	Summary	Travel
GROUP 3/R3	External experts	Travel	Capital	Travel to R3	R3	Capital	Summary	Travel
	ECDC	Travel to Stockholm	Capital	Travel to R3	R3	Capital	Summary	Travel to Stockholm
	EC/WHO/other	Travel	Capital	Travel to R3	R3	Capital	Summary	Travel
GROUP 4/R4	External experts	Travel	Capital	Travel to R4	Travel to R4/travel to capital	Capital	Summary	Travel
	ECDC	Travel to Stockholm	Capital	Travel to R4	Travel to R4/travel to capital	Capital	Summary	Travel to Stockholm
	EC/WHO/other	Travel	Capital	Travel to R4	Travel to R4/travel to capital	Capital	Summary	Travel
GROUP 5/R5	ECDC TL	Travel to Stockholm	Capital	Travel to R5	Capital	Capital	Summary	Travel to Stockholm
	External experts	Travel	Capital	Travel to R5	Capital	Capital	Summary	Travel
	EC/WHO/other	Travel	Capital	Travel to R5	Capital	Capital	Summary	Travel
GROUP 6/R6	ECDC	Travel to Stockholm	Capital	Travel to R6	Travel to R6	Capital	Summary	Travel to Stockholm
	External experts	Travel	Capital	Travel to R6	Travel to R6	Capital	Summary	Travel
	EC/WHO/other	Travel	Capital	Travel to R6	Travel to R6	Capital	Summary	Travel

Table 8. Travel itinerary for team member

Travel itinerary for Mr/Ms [name]							
Date	Departure		Flight	Arrival		Hotel	
	Place	Time		Place	Time	Name	Address

[18] The table should be modified according to framework plan, number of field groups and division of tasks between members of the assessment team.

Table 9. Agenda of assessment visit to [country], [00 Month 2099] to [00 Month 2099]

Date	Place	Team	Morning 1	Morning 2	Afternoon 1	Afternoon 2	Evening	
Sunday 00 Month	Capital		Travel	Assessment team arrives in [city]; transfer to [hotel]		Assessment team meeting Participants: entire assessment team Location: [hotel] 16:00 – 19:00		
Monday 00 Month	Capital		Introductory meeting, Review of the assessment, its objectives, scope, timeline, etc. Participants: entire assessment team and country partners Location: [venue]	Assessment of national-level health governance (Section 1). Participants: [Names] Location: [venue]			Departure: Regional Field Visit Team 1: [destination], [names of traveling team members], [mode of transportation] Team 2: [destination], [names of traveling team members], [mode of transportation] Team 3: [destination], [names of traveling team members], [mode of transportation] Team 4: [destination], [names of traveling team members], [mode of transportation]	
				Assessment of national-level human resource capacity development (Section 2). Participants: [Names] Location: [venue]				
				Assessment of national-level surveillance system (Section 3). Participants: [Names] Location: [venue]				
				Assessment of national-level preparedness and response to public health emergencies (Section 4). Participants: [Names] Location: [venue]				
				Assessment of national-level public health microbiology labs (Section 5). Participants: [Names] Location: [venue]				
				Assessment of national-level disease programme (Section 6). Participants: [Names] Location: [venue]				
Tuesday 00 Month		Team 1:	Car transfer to [district]	Assessment District level Participants: [Names]/institutions visited: [names of institutions]			Car transfer to [region]	
			Assessment at regional level Participants: [Names]					
		Team 2:	Car transfer to [district]	Assessment District level Participants: [Names]/institutions visited: [names of institutions]			Car transfer to [region]	
		Team 3:	Assessment at regional level Participants: [Names]/institutions visited: [names of institutions]					
		Team 4:	Assessment at regional level Participants: [Names]/institutions visited: [names of institutions]					
		Team 5:	Car transfer to [region].	Assessment Regional level Participants: [Names]/institutions visited: [names of institutions]			Car transfer to capital	
		Team 6: Capital	Assessment at national level, health governance (Section 1) Participants: [Names]/institutions visited: [names of institutions]					
Wednesday 00 Month		Team 1:		Assessment at regional level Participants: [names]/institutions visited: [names of institutions]			Transfer to capital: [Mode of transportation]	Assessment team meeting. Participants: entire assessment team Location: [hotel]
				Transfer to capital: [Mode of transportation] Participants: [Names]	-	-	-	
		Team 2:		Assessment at regional level Participants: [Names]/institutions visited: [names of institutions]			Transfer to capital: [Mode of transportation]	
		Team 3:		Transfer to capital: [Mode of transportation] Participants: [Names]	-	-	-	
		Team 4:		Car transfer to [district]	Assessment District level Participants: [names]/institutions visited: [names of institutions]	Assessment District level Participants: [names]/institutions visited: [names of institutions]	Transfer to Capital Transport:	
				Assessment at regional level Participants: [Names], location: [venue]				
		Teams 5 and 6: Capital		Assessment at national level: health governance (Section 1) *** Participants: [Names], location: [venue]				
				Assessment at national level: surveillance system (Section 3) Participants: [Names], location: [venue]				

Date	Place	Team	Morning 1	Morning 2	Afternoon 1	Afternoon 2	Evening	
				Assessment at national level: disease programme (Section 6) Participants: [Names], location: [venue]				
Thursday 00 Month			Capital	Assessment of national-level health governance (Section 1). Participants: [Names] Location: [venue]		Feedback: Assessment of national-level health governance (Section 1). Participants: [Names] Location: [venue]		Assessment team meeting. Participants: Entire assessment team Location: [hotel], [time]
				Assessment of national-level human resource capacity development (Section 2). Participants: [Names] Location: [venue]		Feedback: Assessment of national-level human resource capacity development (Section 2). Participants: [Names] Location: [venue]		
				Assessment of national-level surveillance system (Section 3). Participants: [Names] Location: [venue]		Feedback: Assessment of national-level surveillance system (Section 3). Participants: [Names] Location: [venue]		
				Assessment of national-level preparedness and response to public health emergencies (Section 4). Participants: [Names] Location: [venue]		Feedback: Assessment of national-level preparedness and response to public health emergencies (Section 4). Participants: [Names] Location: [venue]		
				Assessment of national-level public health microbiology labs (Section 5). Participants: [Names] Location: [venue]		Feedback: Assessment of national-level public health microbiology labs (Section 5). Participants: [Names] Location: [venue]		
				Assessment of national-level disease programme (Section 6). Participants: [Names] Location: [venue]		Feedback: Assessment of national-level disease programme (Section 6). Participants: [Names] Location: [venue]		
Friday 00 Month			Capital			Feedback/debriefing meeting. Participants: [Names] and country partners Location: [venue]		
				Assessment team writes report. Location: [hotel]				
Saturday			Travel back					

5.4 Template: plenary meetings

EU assessment team plus national/regional authorities and competent institutions

Date: [00 Month 2099]

Background

The Directorate-General Health and Food Safety (DG SANTE) has requested ECDC to assist the European Commission in assessing [countries'] capacity development, disease surveillance, preparedness and response, and health governance in the area of communicable diseases. On [00 Month 2099], the European Commission invited [country] to accept an assessment mission[19], which will review the communicable disease prevention and control system. On [00 Month 2099], the Minister of Health[20] invited the Commission and ECDC to conduct the assessment which was scheduled for [00 Month]– [00 Month 2099].

In preparation for this assessment, ECDC held a pre-assessment seminar in [00 Month 2099] and several team meetings to analyse data collected by team members and partners in the enlargement country, based on a self-assessment questionnaire.

The assessment visit will start with an **introductory plenary** attended by representatives of the Ministry of Health, public health institutions, representatives of national reference laboratories, and stakeholders from other organisations which will be visited during the course of the mission.

Presentations by national leaders should cover the essential structure and organisation of the systems under assessment; other topics should include an overview of infrastructure, public health capacity and workforce education and training, surveillance and early detection, preparedness and response systems, and laboratory infrastructure, followed by a brief discussion.

Detailed technical presentations and discussions with public health institutions and national reference laboratories should be held in parallel groups. Topics to be covered: the organisation and function of surveillance, early detection and response systems, and laboratory systems.

The **debrief meeting** on [00 Month 2099] will close the assessment activities in the field. During the debriefing, the assessment team gives feedback to the relevant national authorities and stakeholders. This includes provisional key findings with regard to the strengths and perceived opportunities for the development of the country's communicable disease surveillance and response systems and supporting infrastructure.

Table 10. Introductory meeting

Introductory meeting **Date [00 Month 2099]** **Venue: []***			
	Topic	Presenter	Content
09:00	Welcome		Welcome Introduction of the assessment Presentation of the teams Expected outcomes and follow-up of the technical assessment
09:10	EU accession negotiations	DG SANTE	Evaluation of progress in the field of communicable diseases
09:20	EU acquis in communicable diseases	DG SANTE	
09:30	Mission overview	ECDC TL	Overview of the assessment mission; itinerary of the national-level assessment
09:40	Communicable disease system – interim reflections	ECDC TL	Reflections after pre-assessment seminar; reflections after visits to provinces
09:50	Assessment itinerary at the national level		Final agreement on itinerary and logistics
10:00	Discussion		
10:00	Coffee		
10:15	Work in groups		
12:00	Lunch		

[19] Letter of the Directorate General for Health and Food Safety to Mr/Ms [Name] at the Ministry of Health, dated [00 Month 2099].

[20] Letter of Mr/Ms [Name] at the Ministry of Health to the Directorate General for Health and Food Safety, dated [00 Month 2099].

Table 11. Debriefing

Debrief meeting **Date [00 Month 2099]** **Venue: []**			
	Topic	Presenter	Content
09:00	Arrival and signing in		
09:10	Welcome	Country	
09:20	Reflections from the hosts	Country	
09:40	Preliminary observations from the assessment team	ECDC TL and AT members	
10:00	Discussion		
11:45	Final reflections and going forward	European Commission	Final conclusions
12:00	Lunch		

5.5 Template: assessment team meetings

EU Assessment team plus national authorities and competent institutions

Date: [00 Month 2099]

Agenda

09:00 Welcome and introduction
09:15 – 10:45 Introductions to provinces
(5 min/team, headlines about the province and its health/public health systems)

10:45 – 11 30 Thematic system reviews (by section): surveillance and control, microbiology (Sections 3 and 5)
11:30 Coffee
11:45 –12:15 Thematic system reviews (by section): emergency response (Section 4), disease programmes (Section 6), governance and human resources (Sections 1 and 2)
12:15 – 12:30 Synthesis; items to take to national week
12:30 – 13:00 National week assessment
13:00 Lunch
14:00 – 16:00 Meeting wrap-up

	Name	**Signature**
	External experts	
1		
2		
3		
4		
5		
6		
	ECDC staff	
1		
2		
3		
4		
5		
6		
7		
8		
9		
	EU and other institutions	
1		
2		
3		

5.6 Template: technical assessment of enlargement countries: summary of field assessment

Date: [00 Month 2099]

Author: Field leader [name] Signature field leader: ...

Approved: Team leader [name] Signature team leader: ...

Visited region: ...
Visit date: [00 Month 2099]

Assessment field group: [names of group members]
Key summary observations: ...

Summary review

Section 1. Governance

Organisation, capacities, apparent sustainability (funding and resources), leadership and management, apparent effectiveness and efficiency, innovation

[free text]

Section 2. Human resources

Capacity, capabilities (education, training, continuing education)

[free text]

Section 3. Surveillance and control

Capacity, apparent capabilities, effectiveness, efficiency, sustainability of CD case reporting, surveillance processes, routine CD control activities, outbreak recognition and management

[free text]

General system (district level)

- Case confirmation and reporting at the district level: [free text]
- Notification flow at the district level: [free text]
- Data analysis and reports at the district level: [free text]
- Routine communicable disease control activities at the district level: [free text]

System test cases – key findings/issues

System issues regarding ascertainment and reporting, apparent surveillance sensitivity, public health management of cases, outbreak detection and control capacities: [free text]

Outbreak detection, investigation and management: [free text]

General system (regional level): [free text]

Regional objectives and priorities: [free text]

System test cases (STCs) – key findings

System issues regarding ascertainment and reporting, apparent surveillance sensitivity, public health management of cases, outbreak detection and control capacities: [free text]

Outbreak detection, investigation and management: [free text]

Polio surveillance

Parallel surveillance systems

- TB: [free text]
- HIV: [free text]
- STI: [free text]
- Other: [free text]

Sentinel surveillance systems: [free text]

Attached documents:

- Draft flowchart: general surveillance system
- Completed reporting form– last case
- Last outbreak report

- Website link of published reports/published monthly/annual report
- Other: [please specify]

Section 4. Emergency preparedness and response

Capacity, apparent capabilities, effectiveness, efficiency, coordination of civil and public health emergency preparedness and response system: [free text]

Section 5. Microbiology

Capacity, access, range, effectiveness, and efficiency primary diagnostic services, use of reference services, quality and biosafety, relations with public health services and support of communicable disease surveillance and control/outbreak: [free text]

Clinical laboratories in hospitals

- Range of methods/tests
- Samples/isolates referral system
- Reporting lab results/notification

Laboratories

- Range of methods/tests
- Distribution of laboratory testing (clinical samples, screening, environmental samples, etc)
- Samples/isolates referral system
- Reporting lab results/notification
- Epidemiology tasks (if any)

[Free text]

Attached documents:

- Copy of a result reporting form (STC)
- Copy of sample referral
- Summary (aggregate) report

Section 6. Disease programmes

Effective implementation and contribution to national programmes; including data provision for programme monitoring: [free text]

System test cases (STCs)

System issues regarding ascertainment and reporting, apparent surveillance sensitivity, public health management of cases, outbreak detection and control capacities: [free text]

Remarks

New issues raised; system issues resolved/clarified; unexpected findings, 'unknown unknowns', items of good practice/innovation/leadership, 'easy' system improvements, etc.: [free text]

For the attention of the national review team (optional): [free text]

Other remarks (optional): [free text]

Relevant documents – (digital) copies: [free text]

Annex 6. Template for technical assessment report

Assessment mission to [country]

Assessment of country capacities in communicable disease surveillance, prevention and control

Date: [00 Month 2099]

Technical assessment report

[Free text]

Acknowledgments

The assessment team wish to express their appreciation for the support received from the Ministry of Health and the national institute of public health. The team also wish to thank the institutions and individuals who supported the assessment mission.

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