EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Policy on data submission, access, and use of data within TESSy – 2015 revision

Contents

1. Purpose

In accordance with the ECDC founding regulation (Regulation (EC) 851/2004) the EU Member States have to provide ECDC "in a timely manner with the available scientific and technical data relevant to its mission". The European Surveillance System (TESSy) is provided by ECDC in order to collect, analyse and disseminate surveillance data on infectious diseases in Europe.

The founding regulation also calls for ECDC to "develop with the competent bodies of the Member States and the Commission appropriate procedures to facilitate consultation and data transmission and access" (article 11.2). The current procedures were approved by the Management Board in November 2011 (MB23-17 Policy on data submission, access, and use of data within TESSy).

The present policy sets up the principles regarding the submission, access, and use of data in TESSy.

2. Nomination to TESSy

Only nominated individuals will be authorised to log into TESSy according to the TESSy nomination ECDC official procedure. This procedure includes the steps and conditions for nominating individuals from EU/EEA countries, WHO-EURO staff and collaborating countries, non-EU/EEA countries other than WHO-EURO collaborating countries, the European Commission and other EU bodies and institutions, and ECDC staff and their contractors.

Nominated TESSy users will be provided with a specific type of user account, permissions and credentials according to the procedure and principles approved by ECDC.

3. Confidentiality of data principle

Data stored within TESSy are confidential1 and they will be treated as such. Previously published data in aggregated format are not considered confidential.

All National Coordinators or the legal representative of nominating entities are responsible for explaining and enforcing the confidentiality principles to the users they nominate.

4. Data handling

The data originate from Member States, who submit it in compliance with the EU regulations including EC decisions (notably Decision 1082/2013/EU), and other data providers who submitted in accordance with this policy. ECDC is the data controller, holds the data in its trusteeship, and can assist Member States in data uploading and reporting. ECDC is also entrusted with the technical implementation of the publication of the data and the granting of data access in accordance with this policy.

5. Data submission to TESSy

Data submission to TESSy has to be consistent with Commission Decision 1082/2013/EU and with its implementing acts. Commission Decision 1082/2013/EU explicitly specifies in Chapter III, article 6, paragraphs 3 and 4 that:

"*3. The national competent authorities referred to in paragraph 2 shall communicate the following information to the participating authorities of the epidemiological surveillance network:*

(a) comparable and compatible data and information in relation to the epidemiological surveillance of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1);

(b) relevant information concerning the progression of epidemic situations;

[1] The use of the term "confidential information" in this context is not intended to mean "EU classified information" within the meaning of Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information.

(c) relevant information concerning unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries.

4. When reporting information on epidemiological surveillance, the national competent authorities shall, where available, use the case definitions adopted in accordance with paragraph 5 for each communicable disease and related special health issue referred to in paragraph 1."

Where Article 2(1) refers to:

"*(a) threats of biological origin, consisting of:*

(i) communicable diseases;

(ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases (hereinafter 'related special health issues');"

Data providers not subject to Commission Decision 1082/2013/EU may submit data to TESSy under the same conditions as data providers under Decision 1082/2013/EU. For this purpose, specific agreements with the data providers (or the organisations to which they belong) are concluded.

ECDC may upload any publicly available data to TESSy, provided that such upload is allowed under applicable legislation.

5.1. Removal of personal identifiers of data (Pseudonymisation)

All personal identifiers will be removed from the data set by the Data Submitter prior to uploading case-based data into TESSy. Where unique record identifiers are used to report case-based data, they must be anonymised and must not be traceable to individuals by ECDC. ECDC should not be able to use the information in its possession to identify any persons.

6. Access and use of TESSy data

6.1. Legal Background

6.1.1. ECDC, EU/EEA countries, European Commission, EU bodies, International Organisations and other entities

In accordance with its Founding Regulation, ECDC, in coordination with Member States and the Commission, shall coordinate the data collection, validation, analysis and dissemination of data at Community level. The data collected need to be accessed and used by ECDC and the Member States in order to perform their respective tasks.

In addition, based on the "Common guidelines on practical arrangements for the sharing of scientific data between the scientific committees and panels of European Agencies and the scientific committees of the Commission" of the European Commission - Directorate-General Health & Consumers of 10 November 2008, access to this data can also be granted to other European bodies.

International organisations and other entities may need to gain access whenever this is necessary to serve the public interest of protecting public health in the European Union. These users may either be granted direct access or case-by-case access as described below.

6.1.2. Third Parties

Third parties are defined as persons or institutions that are not part of the nominated TESSy user group and that are not the entities under the legal basis described in 6.1.1 (e.g. academic institutions, universities, non-EU public health agencies, non-governmental organisations, commercial companies and individual scientists or beneficiaries of ECDC).

The data contained in the TESSy database, as any data held by ECDC, is subject to the provisions of Regulation (EC) 1049/2001.

Under this Regulation, any member of the public has a right to access to the data, with the exception of data for which one of the exceptions in Article 4, paragraphs 1 to 3 of Regulation 1049/2001, applies.

For TESSy data, the most relevant exceptions are the following:

"The institutions shall refuse access to a document where disclosure would undermine the protection of:

(a) the public interest as regards:

— public security,

— defence and military matters,

— international relations,

— the financial, monetary or economic policy of the Community or a Member State;

(b) privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data.

2. The institutions shall refuse access to a document where disclosure would undermine the protection of:

— commercial interests of a natural or legal person, including intellectual property, — court proceedings and legal advice,

— the purpose of inspections, investigations and audits, unless there is an overriding public interest in disclosure.

3. Access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure.

Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure."

In order to refuse access on the basis of an exception, a concrete and specific examination of the documents to be disclosed has to be carried out, and the application of the exception has to be duly justified. If possible, parts of the document which do not fall under one of the exceptions still will need to be disclosed. This needs to be assessed on a case-by-case basis.

Even if it is found that the data requested concerns personal data, it is to be noted that in accordance with Regulation 45/2001 access may be granted if the requester establishes that the data are necessary for the performance of a task carried out in the public interest. A request for use of the data for research purposes is considered to be a task carried out in the public interest.

Member States and other data providers may request ECDC not to release specific subsets of TESSy data they uploaded when the exceptions of the Regulation 1049/2001 apply. However, for any such request, a detailed reasoning on why an exception applies and which data are concretely concerned (i.e. is it possible to remove the concern by redaction/removal of some elements) must be provided to ECDC, as ECDC is obliged to provide reasons for non-disclosure towards the recipient.

6.2. Direct access and use of TESSy data

Direct access to data refers to validated data (i.e. data validated by the data providers according to the metadata set validation rules) within TESSy.

The following user categories are entitled to have direct access to TESSY data as nominated users, provided that they comply with all conditions for obtaining such access (see section 6.2.1 below):

- All ECDC personnel can access data when needed to perform their tasks (e.g. analysis of data, providing support to MS, …).
- European Commission staff and other European Agency personnel may also access and analyse the data upon request.
- In the Member States, access to aggregated and case-based data will be given to nominated users according to their specific permissions.
- ECDC and the WHO Regional Office for Europe may jointly coordinate the surveillance of some diseases for the WHO European Region using TESSy as the joint database. In this context,
    - Nominated users from the WHO Regional Office for Europe may have direct access to aggregated and case-based data for all countries for these diseases after training;
    - Nominated users in the non-EU/EEA countries participating in the surveillance of these diseases may have direct access to aggregated data for all countries and case-based data for their own country for these diseases after training.
- In specific cases, where this is necessary and proportionate for the public interest of protecting public health in the European Union, ECDC may grant other parties direct access to specific subsets of TESSy data. Such additional direct access shall in each case require the authorization of the Director. Further details regulating the access may be set out in agreements concluded with the party.

6.2.1. Conditions for direct access to TESSy data

Before gaining direct access to TESSy data, all users must undergo training in the concepts, principles and use of TESSy and TESSy data. This training will be provided by ECDC either in a workshop or online.

Before being granted direct access to TESSy data, all users must read and accept the terms of service. These terms set out basic conditions of confidentiality, conditions of access and the conditions for use of the data. Any user may also be required to comply with standard security requirements.

If the collaboration is not defined in an existing legal act, an agreement setting out the terms of the collaboration shall be concluded.

6.3. Requests for access subsets of TESSy data

For some individuals from the institutions, organisations and entities who are entitled to gain direct access to TESSy, it is neither practicable nor necessary to obtain this direct access. Nevertheless, for the same reasons that direct access can be granted to users under section 6.2, access may be granted to these users on a case-by-case basis.

Additionally, other third parties under the legal basis described in 6.1.2 can request and have access to subsets of TESSy data for research purposes following the same procedures.

Requests from thirds parties for purposes other than research shall be submitted following the instructions of access to document requests on ECDC's website.

Third party requests from non-EU/EEA countries will be treated by ECDC subject to the availability of resources.

These principles apply to both case-based and aggregated data access requests.

6.3.1. Case-based and non-published aggregated TESSy data requests

To receive a subset of case-based or non-published aggregated TESSy data, requesters must submit a request for data to ECDC using the prescribed form “Request for TESSy data for research purposes” specifying the research or tasks in the public interest, when applicable, that the data will be used for.

Before receiving the data each recipient shall sign the “Declaration of commitment”, which includes the “ECDC data disclaimer” and the “Conditions for publishing note” for each person handling the data.

Data requested for research purposes will be released only to specific identifiable individuals who will be responsible for the use of the data and who will be responsible for compliance with confidentiality when this applies. The recipient shall assure that any person working for him on the project also signs the “Declaration of commitment” and adheres to the conditions set out therein.

The data will be made available to the applicants, after a quality check by ECDC experts, as an extraction from TESSy in electronic format.

Member States whose data are part of the extraction will be informed.

In the case a Member State does not agree to disclosure, ECDC will liaise with the Member State to assess the applicability of exceptions under Regulation EC/1049/2001 with the aim to prevent disclosure. With that respect, will request the Member State to provide justifications to object to disclosure as described in article 4, 1st to 3rd paragraph of Regulation EC/1049/2001. ECDC will take exceptions and justifications provided by Member States into account when responding to the request for disclosure of the requested data for research purposes.

6.3.2. Aggregated already published TESSy data requests

Aggregated already published TESSy data can be made available to applicants by submitting a “Request for TESSy data for research purposes”. Following such a request, data will be made available subject to technical feasibility and in aggregations different from the ones available in the original ECDC publication.

There is no need to sign a declaration of commitment. Nevertheless, the applicant shall consider whether a breach of confidentiality is likely due to a low cell count and make no use of the identity of any person discovered inadvertently. Additionally, the conditions for publishing shall be respected and will be communicated to the applicant together with the data.

6.4. Peer review group

For instances in which ECDC has doubts about the application of this policy, on the validity of the requests or on the reliability of the data recipient, a peer review group will be established and consulted. The peer review group will consist of three National surveillance focal points (nominated by the National coordinator of the competent body) and two ECDC experts (nominated by the Head of the ECDC surveillance and response support unit). This group, upon ECDC request, will also advise on any contention or complaint about access to TESSy data.

6.5. Accessibility of aggregated data for the general public

TESSy data can be made accessible by ECDC on its web site to the general public as aggregated data summary reports. The predefined series of aggregate reports by country or disease will be agreed upon with the Member States. ECDC may define the format and technical tools for access to this data.

Force majeure in the form of serious threats to public health may allow divulgence by ECDC of aggregated data in derogation to this provision.

6.6. Data publication policy

Any publication arising from data obtained from TESSy should fulfil the “Conditions for Publishing”. Recipients will be informed about these conditions and, when applicable, recipients will be asked to accept these conditions in their declaration of commitment.

ECDC considers reporting to parties other than the recipients which are named in the request or their contractors as publishing and the conditions for publishing has to be respected.

7. Data protection and other relevant legislation

These procedures comply with “REGULATION (EC) No 45/2001 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”.

The procedures apply without prejudice to Decision 1082/2013/EU and Decision 2000/57/EC and are guided by Article 15(1) and (3) of the Treaty on the Functioning of the European Union, EC Regulations 1049/2001, 178/2002, 726/2004, 851/2004, 1907/2006, 2008/721/EC;

When developing this policy, the European Commission - Directorate-General Health & Consumers “Common guidelines on practical arrangements for the sharing of scientific data between the scientific committees and panels of European Agencies and the scientific committees of the Commission” of 10 November 2008 – Brussels- and the opinions of the European Data Protection Supervisor of 03.09.2010 and 09.06.2015 (Case 2009-0474) on TESSy and, as well as opinion 01/2010 of Data Protection Working Party have been taken into account.

8. Validity of this policy

This policy will be subject to periodic reviews taking into account the experience accrued, the flow of requests for data and eventual new legislation, instructions from the European Commission and opinions of the European Data Protection Supervisor.