



EUROPEAN COMMISSION

PROTECTION OF YOUR PERSONAL DATA

This privacy statement provides information about the processing and the protection of your personal data.

Processing operation: *JRC Central Database for EUROCAT (European network for the surveillance of congenital anomalies)*

Data Controller: *European Commission Joint Research Centre, Directorate F – Health Consumers and Reference Materials, Unit F.1 – Health in Society*

Record reference: **DPR-EC-01972**

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1. Introduction

The European Commission (hereafter 'the Commission') is committed to protect your personal data and to respect your privacy. The Commission collects and further processes personal data pursuant to [Regulation \(EU\) 2018/1725](#) of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data (repealing Regulation (EC) No 45/2001).

This privacy statement explains the reason for the processing of your personal data, the way we collect, handle and ensure protection of all personal data provided, how that information is used and what rights you have in relation to your personal data. It also specifies the contact details of the responsible Data Controller with whom you may exercise your rights, the Data Protection Officer and the European Data Protection Supervisor.

The information in relation to processing operation "JRC Central Database for EUROCAT" undertaken by the Unit JRC.F.1 (Health in Society) of the Directorate F (Health, Consumers and Reference Materials), European Commissions' Joint Research Centre is presented below.

2. Why and how do we process your personal data?

EUROCAT is a European network of population-based registries, which has been active since 1979. The relevance of the EUROCAT network is to support recommendations, policies and decision-making in public health, and to contribute to the research on reducing mortality, anomalies, impairment and disabilities, improving quality of life, and promoting best practices for prevention and care for European citizens.

According to the Administrative Arrangement with DG SANTE, JRC developed the EU Platform for Rare Diseases Registration (EU RD Platform). The JRC Central Database for EUROCAT is part of the EU RD Platform. Registry members of EUROCAT signed a collaboration agreement with JRC that covers the transfer of historical data and the transmission of prospective data to the JRC-EUROCAT Central Registry.

The Unit JRC F.1 (Health in Society) collects and uses your personal information for epidemiological surveillance and research purposes.

Your personal data will not be used for an automated decision-making including profiling.

3. On what legal ground(s) do we process your personal data

We process your personal data, because, according to Article 5(1)(a) of Regulation (EU)2018/1725, the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body.

The processing operations on personal data in the context of the "JRC Central Databases for EUROCAT " are necessary and lawful under:

- 1) Communication from the Commission on Rare Diseases: Europe's Challenges. [Com(2008) 679 final];
- 2) Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02);
- 3) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare;

4) Administrative Arrangement between DG SANCO and DG JRC on the EU Platform for Rare Diseases Registration;

5) Treaty on the Functioning of the European Union, Title XIV (Public Health) Article 168.

We process special categories of personal data, therefore Article 10 of Regulation (EU)2018/1725 applies. The JRC Central Database for EUROCAT includes data concerning health, a special category of data. The health data include medical descriptions, medical diagnosis and tests results, medical classifications, and socio-demographic data (maternal education, socioeconomic status of mother and father, migrant status).

We process special categories of data indicated in Section 4, because, according to Article 10(2) of Regulation (EU)2018/1725:

(g)- the processing is necessary for reasons of substantial public interest, on the basis of Union law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject;

(h)- the processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;

(i)- the processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices, on the basis of Union law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy; or

(j)- the processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes based on Union law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

4. **Which personal data do we collect and further process?**

We have obtained your personal data from the registries that are members of the EUROCAT network and signed a collaboration agreement with the JRC.

The main role of the JRC EUROCAT Central Database is to host historical data and new prospective data on citizens with congenital anomalies, as well as information on stillbirths and terminations of pregnancy. The registry members of the EUROCAT network collect personal data on European citizens with rare conditions. Annually the registries submit data to JRC EUROCAT Central Database on all cases born on a specific year in the geographical region covered by the registry.

For the purposes of communication with local registries, the cases are identified by a unique identifier assigned by each register with its own rules (a maximum of 11 characters long, consisting of numbers, letters or both). These codes are used for transmission of individual data to the JRC EUROCAT Central Registry and they are for sufficiently large groups so that individual cases cannot be identified at JRC EUROCAT Central Registry.

The personal data collected and further processed are:

- **Identification data:** the cases are identified for the purposes of communication between JRC and local registries by a unique identifier. Other identification data: birth date, sex, multiple birth, birth weight, gestational age, death date, date of birth of the mother.
- **Geographic area:** residence of the mother according to the coverage of the registry [population-based registries collect data on all mothers from a defined geographical area (no additional information is available, e.g. postcode or address).]
- **Health data:** medical descriptions, medical diagnosis and tests results, medical classifications, and socio-demographic data (maternal education, socio-economic status of mother and father, migrant status).

These data combined can correspond to a unique individual. If matched to other sets of data (not available at JRC), an individual can be identified.

The provision of personal data is not mandatory.

5. How long do we keep your personal data?

The Unit JRC F.1 only keeps your personal data for the time necessary to fulfil the purpose of collection or further processing. Keeping past data together with data received annually is a requirement for identifying changes in occurrence of events of interest over time and place. The main purpose of the databases is to be used for epidemiologic surveillance, which includes statistical monitoring of clusters and trends over time. The continuous accrual of cases in the databases allows estimating and comparing annual occurrence probabilities. Once included, all data are kept in the JRC Central Databases for EUROCAT and SCPE for 25 years. After that period all variables containing personal data are cancelled.

6. How do we protect and safeguard your personal data?

All personal data in electronic format (e-mails, documents, databases, uploaded batches of data, etc.) are stored on the servers of the European Commission. All processing operations are carried out pursuant to the [Commission Decision \(EU, Euratom\) 2017/46](#) of 10 January 2017 on the security of communication and information systems in the European Commission.

In order to protect your personal data, the Commission has put in place a number of technical and organisational measures. Technical measures include appropriate actions to address online security, risk of data loss, alteration of data or unauthorised access, taking into consideration the risk presented by the processing and the nature of the personal data being processed. Organisational measures include restricting access to the personal data solely to authorised persons with a legitimate need to know for the purposes of this processing operation.

7. Who has access to your personal data and to whom is it disclosed?

Access to your data is provided to authorised staff according to the “need to know” principle. Such staff abide by statutory, and when required, additional confidentiality agreements.

The recipients of the data are the staff working under the authority of the controller at JRC and the processors working on behalf of the controller.

All the results of the data analysis performed on individual data are published in aggregated form and do not refer to personal data. The recipients of the results of the data analysis are DG

SANTE (scientific reports), academic and lay publications, and publicly available websites (public reports).

All members of the EUROCAT network have access to anonymised data (not containing variables with personal data) for research purposes. Access to these data is granted after a formal request procedure, which includes objectives and a brief study description, as well as a detailed study protocol. The request must be approved by the EUROCAT Management Committee who assesses the relevance of the study and the reliability of the scientific protocol.

Upon study approval by the Management Committee, according to the Collaboration Agreement the JRC Central Registry asks from all the registries, which participate in the study in subject a formal approval to release the data. After approval the JRC Central Registry releases the agreed datasets and keeps a copy of all data and related documentation for 10 years on a secure server.

The information we collect will not be given to any third party, except to the extent and for the purpose we may be required to do so by law.

8. What are your rights and how can you exercise them?

You have specific rights as a 'data subject' under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase your personal data and the right to restrict the processing of your personal data. Where applicable, you also have the right to object to the processing or the right to data portability.

You have the right to object to the processing of your personal data, which is lawfully carried out pursuant to Article 5(1)(a).

You can exercise your rights by contacting the Data Controller, or in case of conflict the Data Protection Officer. If necessary, you can also address the European Data Protection Supervisor. Their contact information is given under Heading 9 below.

Where you wish to exercise your rights in the context of one or several specific processing operations, please provide their description (i.e. their Record reference(s) as specified under Heading 10 below) in your request.

9. Contact information

- The Data Controller

If you would like to exercise your rights under Regulation (EU) 2018/1725, or if you have comments, questions or concerns, or if you would like to submit a complaint regarding the collection and use of your personal data, please feel free to contact the Data Controller, Unit JRC F.1, JRC-F1-Secretariat@ec.europa.eu.

- The Data Protection Officer (DPO) of the Commission

You may contact the Data Protection Officer (DATA-PROTECTION-OFFICER@ec.europa.eu) with regard to issues related to the processing of your personal data under Regulation (EU) 2018/1725.

- The European Data Protection Supervisor (EDPS)

You have the right to have recourse (i.e. you can lodge a complaint) to the European Data Protection Supervisor (edps@edps.europa.eu) if you consider that your rights under Regulation

(EU) 2018/1725 have been infringed as a result of the processing of your personal data by the Data Controller.

10. Where to find more detailed information?

The Commission Data Protection Officer (DPO) publishes the register of all processing operations on personal data by the Commission, which have been documented and notified to him. You may access the register via the following link: <http://ec.europa.eu/dpo-register>.

This specific processing operation has been included in the DPO's public register with the following Record reference: DPR-EC-01972. - JRC Central Databases for EUROCAT and SCPE.