EUROPEAN COMMISSION



PROTECTION OF YOUR PERSONAL DATA

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

Processing operation: Information Platform for Chemical Monitoring (IPCHEM) - Human

Biomonitoring module (HBM data)

Data Controller: European Commission, JRC.F.3

Record reference: DPR-EC-09766

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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 "Information Platform for Chemical Monitoring (IPCHEM) — Human Biomonitoring module (HBM data)", undertaken by JRC.F.3 is presented below.

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

<u>Purpose of the processing operation</u>:JRC.F.3 collects and uses your personal information to develop, maintain and manage the IPCHEM Human Biomonitoring module (HBM data).

IPCHEM is an information platform, developed and managed by the JRC, under mandate of DG Environment. It provides access to chemical monitoring data, collected and owned by different European and National institutions and research organisations. IPCHEM promotes a more coherent approach to the generation, collection, storage and use of chemical monitoring data in relation to humans and the environment, through the creation of a platform for chemical monitoring data, as requested to the Commission by the COM (2012) 252. This will help identify links between exposure and epidemiological data in order to explore potential biological effects and lead to improved health outcomes.

IPCHEM is developed as a collaborative platform among the European Commission Services (ENV, SANTE, RTD, GROW, EMPL and JRC) and EU Agencies (EEA, ECHA, EFSA). DG ENV ensures coordination and decision making with other services on the scope, direction and possible functionalities for IPCHEM. The JRC is responsible for the scientific coordination and technical design and development of IPCHEM, for its maintenance and operation and for data handling and integration into IPCHEM.

The platform allows access to:

- a) Data collections containing chemical concentration values collected in different media (soil, water, air, products, food, feed, humans) and
- b) Metadata pages where general information for each data collection is displayed.

To be part of the IPCHEM platform, each Data Controller must compile and sign the IPCHEM Participation Form, annexed to the IPCHEM Data Policy and subsequently provide it to the JRC-IPCHEM team.

The data collections are classified according to 4 thematic modules:

1) Environmental monitoring data,

- 2) Human Biomonitoring (HBM) data,
- 3) Food and Feed monitoring data,
- 4) Products and Indoor air monitoring data.

For modules 1, 3 and 4, the data submitted to the JRC IPCHEM team is anonymised data, except the contact details of the data owner/provider, which are part of the metadata information, covered by record DPR-EC-00213 - Information Platform for Chemical Monitoring (IPCHEM) general data processing.

The present record covers specifically the processing of the data in module 2 (Human Biomonitoring) where the data submitted to the JRC IPCHEM team can be aggregated/anonymised or pseudonymised data.

Aggregated/anonymised data

Before submitting the data, the data owner/provider will aggregate the data to a level where the individual subjects are no longer identifiable, the resulting dataset can be qualified as anonymous.

For some purposes, aggregated data might be sufficient, and data minimization principle can be applied. However, to analyse e.g. combined exposure to multiple chemicals to identify prevalent chemical mixtures, individual level (pseudonymised) are needed.

Pseudonymised data

Pseudonymised data means personal data that can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

For this specific data collections, pseudonymised Human Biomonitoring (HBM) data, the JRC IPCHEM team will proceed as joint controller with the HBM data provider (e.g. consortium partners of research projects like HBM4EU or PARC), controllers of the pseudonymised data and responsible for the safekeeping of the key that could allow the re-identification of the individuals. The JRC IPCHEM team does not receive this key.

Joint controllership agreements according to Article 28 (Regulation (EU) 2018/1725) will be established between the JRC IPCHEM team and the research consortium HBM4EU or any other HBM data provider, to regulate the processing of the data and for hosting the pseudonymised data in the IPCHEM hosting facilities.

The HBM data provider directly uploads the data in the hosting facilities and manages the access of authorised users. In the IPCHEM Data Policy (Article 6) it is clearly stated that the JRC IPCHEM team can accept only data which are fully compliant with national ethics and legal requirements and with any exceptional accessibility regimes imposed to the data by the data owner/provider/controller, and based on regulatory or on valid and legitimate contractual obligations. It is the full responsibility of the data owner/provider/controller to be compliant with these requirements and restrictions.

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)(d) of Regulation (EU)2018/1725, you have given consent to the processing of your personal data for one or more specific purposes.

We process **special categories of personal data**, therefore Article 10 of Regulation (EU) 2018/1725 applies. We collect **health data**: The "human biomonitoring (HBM) module" of IPCHEM contains data on concentrations of chemicals in human matrices, such as blood, urine, human milk, saliva, hair, teeth, faeces etc. which can be considered "health data". Additional variables covered in the data sets alongside the chemical concentrations may include information related to food consumption, socioeconomic factors, educational information, etc for the study participants.

Such HBM data are either aggregated / anonymous or individual level pseudonymised data. The key for re-identification will not be transferred.

We process special categories of personal data indicated in Section 4, because:

(a) you have given explicit consent to the processing of your personal data for one or more specified purposes.

In data sets that are generated in recent human biomonitoring studies, where the study directors are planning to provide data to IPCHEM from the beginning of the study, you are directly asked whether you consent to share data at EU level with EU institutions. No studies without explicit consent will be included in IPCHEM.

Sharing the data at EU level allows deriving a wider view on chemical exposure of humans (in the context of consumer and worker exposure), looking into spatial distributions, temporal trends, and links to the development of specific diseases. Also the impact of regulatory measures to reduce exposures can be assessed using HBM data. The processing is compatible with the purpose originally agreed to by you in the consent form. Only pseudonymised data are processed, the key for re-identification will never be made available to the IPCHEM team.

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

In order to carry out this processing operation JRC.F.3 collects the following categories of personal data:

Data on concentrations of chemicals in human matrices (such as blood, urine, human milk, saliva, hair, teeth, faeces etc.) which can be considered "health data". Such HBM data are accepted as aggregated / anonymous data or individual level pseudonymised data. Additional parameters that may be provided for interpretation of the data comprise information such as on the study population (e.g. sex, age, height or weight, educational level) and environmental factors (e.g. urban vs rural environment). If the number of individuals is too small to prevent reidentification only categories of information instead of the exact information will be included, e.g. category of age range rather than the exact age in months. Geographical data or location are generalised and usually represented by an area (e.g. a country or a region).

The provision of personal data is not mandatory.

We have obtained your personal data from data controllers of data from HBM studies, such as consortium partners of the HBM4EU H2020 project or other HBM studies for which participants have agreed in the consent form to share their data with EU institutions. In the case of

participants being minors, the parents or legal guardians were informed and have signed the consent form.

5. How long do we keep your personal data?

JRC.F.3 only keeps your personal data for the time necessary to fulfil the purpose of collection or further processing, namely for the time agreed in the original consent form and joint controller agreement. If not specified, data should be kept for a maximum period of 25 years in order to allow research into long-term time trends of exposure and links to developing diseases which occur with delay after exposure.

However, if a data provider at the end of a study destroys the key for re-identification, the data can be considered anonymous and no longer pseudonymous. Where applicable, if studies are continued over longer periods, updates of data sets over time are made to ensure accuracy and completeness.

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 <u>Commission Decision (EU, Euratom) 2017/46</u> 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 in place. 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.

Several safeguards are implemented in order to protect your identity:

- JRC only receives pseudonymised data: key-coded data
- Only the information needed is collected
- Technical safeguards (such as EU login authentication and encryption of pseudonymised data) have been implemented.

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

Access to your personal data is provided to the Commission staff responsible for carrying out this processing operation and to authorised staff according to the "need to know" principle. Such staff abide by statutory, and when required, additional confidentiality agreements.

If a consortium partner, EU Member State authority or EU agency requests to use the data and the request is considered compatible with the original purpose in the consent form, a data transfer agreement will be established and a workflow for data minimisation will be followed. The controller might transfer your personal data upon request to recipients in third countries after having established a specific agreement and checking compliance with the original consent. The HBM providing data controller will grant access to the relevant (minimised) information via the IPCHEM Share system allowing the user to download the minimised and pseudonymised data for further processing. This concerns the following recipients in a third country or to an international organisation in accordance with Regulation (EU) 2018/1725:

Data will be transferred to **Norway and Iceland**. EU data protection rules apply to the European Economic Area (EEA), which includes all EU countries and non-EU countries Iceland, Liechtenstein and Norway.

In the case of **Switzerland, the United Kingdom and Israel**, the controller will transfer your personal data based on:

- <u>adequacy decision</u> of the Commission for a specific country / commercial sector (Article 47 of Regulation (EU) 2018/1725).

In the case of **North Macedonia**, the controller will transfer your personal data based on:

a derogation for specific situations in accordance with Article 50.1 (a) of Regulation (EU) 2018/1725): you have explicitly consented to the proposed transfer, after having been informed of the possible risks of such transfers for the data subject due to the absence of an adequacy decision and appropriate safeguards

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 consented to provide your personal data to JRC.F.3 for the present processing operation. You can withdraw your consent at any time by notifying the Data Controller. The withdrawal will not affect the lawfulness of the processing carried out before you have withdrawn the consent.

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:

jrc-ipchem-support@ec.europa.eu

- The Data Protection Officer (DPO) of the Commission

You may contact the Data Protection Officer (<u>DATA-PROTECTION-OFFICER@ec.europa.eu</u>) 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-09766 - Information Platform for Chemical Monitoring (IPCHEM) – Human Biomonitoring module (HBM data).