

IPCHEM - The Information Platform for Chemical Monitoring: *Data Policy*



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General issues

What is IPCHEM and what are its objectives

IPCHEM ("Information Platform for Chemical Monitoring") is a single access point for locating and retrieving chemical occurrence data across all possible media (e.g. environment, humans, food/feed, indoor air and consumer products) in the European Union¹. IPCHEM is being operated by European Commission services and European Union agencies.

The objective of IPCHEM is to increase the accessibility to and to facilitate use of available data mentioned above in order to help better assessing the overall exposure of environment and humans to chemicals and chemical mixtures.

Data are made available via IPCHEM only with the authorisation of the data owner/provider.

Article 1. Objectives and scope of the IPCHEM Data Policy

1. The IPCHEM Data Policy:

- a) Defines and formulates the principles and conditions that govern provision, management, access, use and re-use of chemical monitoring data, metadata and related information that are retrievable through the IPCHEM platform, and their re-combination, across and beyond the IPCHEM thematic modules;
- Lays down rules for effective and efficient implementation of the principles described below and conditions applicable to chemical monitoring data and metadata retrievable through the IPCHEM platform;
- c) Promotes transparency and good governance practices in order to enable and facilitate a coordinated and integrated approach for the access, use and re-use of chemical monitoring data and metadata;
- d) Promotes and implements the overarching principles of free, full, open and timely access to all kinds of chemical monitoring data where possible, whilst recognizing and respecting relevant legislative provisions and government guidance regarding protection of personal data, ethical considerations, data ownership and intellectual property rights that apply to such data.
- 2. The IPCHEM Data Policy ensures compliance with the following principles:
 - a) Protecting the integrity, transparency, and traceability of chemical monitoring data and of their use for analysis and forecasts;
 - Recognising and respecting data protection legislation, both at the European Union and national levels, in particular Regulation (EU) 2018/1725 (henceforth "EUDPR²") and Regulation (EU) 2016/676 (henceforth "GDPR³")
 - c) Recognising and respecting intellectual property rights of IPCHEM Data Providers and Data Owners as defined in agreement with them;

¹ https://ipchem.jrc.ec.europa.eu/

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, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (Text with EEA relevance.) (OJ L 295, 21.11.2018, p. 39–98)

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

- d) Using European or international standards and services on data interoperability and the principles set out in the INSPIRE Directive⁴ and in the Shared Environmental Information System (SEIS)⁵.
- 3. Subject to the principles above, this IPCHEM Data Policy envisages a regime of Open Access to data by default for making chemical monitoring data retrievable through the IPCHEM platform for further use and re-use, and outlines the conditions that allow Data Providers and Data Owners to impose special accessibility regimes to restrict access to their data.

Article 2. Definitions

Aggregated data mean the combination of several single measurement data. Individual measurements are replaced with summary statistics based on those measurements. Aggregation can be based on various types of attributes, e.g. spatial or temporal. Aggregation is conducted involving sufficiently high numbers of individual measurements so as to ensure that the resulting information is not considered as information relating to an identified or identifiable natural person under Art. 3 EUDPR and 4 GDPR, taking into account the criteria in recitals 25 EUDPR and 26 GDPR. Summary statistics are recorded into a structured format and expressed as numeric value and coupled with all the attributes needed to contextualise and interpret the data values and to document their quality and reliability.

Anonymous information means information which does not relate to an identified or identifiable natural person, including personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This can be achieved for example by aggregating data to a sufficient level. The principles of data protection do not apply to anonymous information (see GDPR Recital 26, EUDPR Recital 16).

Chemical monitoring data mean a series of measurements of defined variables which are measured for a specific purpose according to a predetermined time schedule to determine the spatial-temporal level of concentration of chemical(s) in various media (e.g. environmental media, food and feed, human bodies, consumer products and indoor air).

Consent of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her (see GDPR Article 4(11), EUDPR Article 3(15)).

Data controller means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data. A data provider or data owner is the data supplying controller. For pseudonymised human biomonitoring data hosted in IPCHEM, the data supplying controller will be joint controller with the JRC as the Scientific and Technical lead for IPCHEM.

Data Owner means the entity that holds the legal ownership of data, and as such can authorise or deny access to data from IP perspective. The Data Owner may or may not be distinct from the Data Controller.

Data Processor means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller (see GDPR 4(8), EUDPR 3(12)).

Data Provider means the entity (nominated by the Data Owner) in charge of the collection, acquisition, production, management, quality control and/or publication and dissemination of data; this definition may include Commission Services, EU Agencies and third parties. The Data Provider may or may not be distinct from the Data Owner.

Filtered single measurement data mean single measurement data where certain values or attributes (e.g. personal identity and/or the sample source location) are removed or not made accessible.

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⁴ Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE), OJ L 108, 25.4.2007, p. 1–14.

⁵ http://www.eea.europa.eu/about-us/what/shared-environmental-information-system-1

Free access means that chemical monitoring data are retrievable by the user without charge, or without incurring costs for the data reproduction and distribution.

Generalised single measurement data mean single measurement data where a process of generalisation (e.g. spatial) has been applied to some attributes (e.g. reducing the precision of the coordinates of the sample source location).

Metadata mean data that define and describe other data. The metadata are a series of structured information relating to all the measurement data in one data collection and common to all the measurement data, which facilitate understanding, tracing and working with the data. In particular, metadata means a set of descriptive elements providing information on the "container of the data" (i.e. the title of a data collection, the abstract describing this data collection, etc.). For aggregated data, the metadata includes also information about the statistical method used for the aggregation. For filtered or generalised data, the metadata also includes information about the type of filtering or the generalisation applied.

Module Coordinators mean EU organisations responsible for the coordination of the IPCHEM thematic modules of IPCHEM. The European Environmental Agency (EEA) is module coordinator for environmental monitoring data and human biomonitoring data. The European Food Safety Authority (EFSA) is module coordinator for food and feed monitoring data. JRC is module coordinator for products and indoor air monitoring data.

Open Access means that data are available to the user without the user making a specific request or obtaining a specific authorisation for it.

Open Data principles mean the principles governing the open access to the IPCHEM chemical monitoring data.

Personal data means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (see GDPR Article 4(1), EUDPR 3(1)).

Project Coordinator means an individual or organisational entity who acts as the coordinator of a research project and its associated Project Group.

Project Group means a temporary or permanent structured group of partners (individual or organisational entities) contributing to the planning and execution of a specific research project. It consists of users nominated by the project coordinator through an agreement or formal nomination procedure and who have specific rights to access and use the chemical monitoring data that are generated, collected or analysed in the context of the specific project.

Pseudonymisation means the processing of personal data in such a manner that the personal data 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 (see GDPR Article 4(5), EUDPR Article 3 (6)). This applies to single measurement human biomonitoring data hosted in IPCHEM, for which the data provider/owner and JRC as the Scientific and Technical lead of IPCHEM are joint controllers. The key for re-identification stays with the data owner/provider and will not be transferred to the JRC.

Single Measurement data mean individual concentration of chemical(s) measured in a specific medium collected via a specific sampling technique at a specific location and time, and later analysed and recorded into a structured format as a numeric value. Single Measurement data also contain additional attributes needed to interpret the specific numeric value and assess its quality and reliability (e.g. date and location of sampling, name of sample, limit of detection, limit of quantification, uncertainty of measurement, quantification with/without authentic standard, with/without use of internal standard, etc.). This represents the highest possible degree of detail of data retrievable through IPCHEM.

Timely access means that data are released as quickly as they are produced or acquired, or as soon as they can be made available to the users.

User means persons or legal entities accessing the IPCHEM data through the IPCHEM interface.

User group means a group of persons or legal entities that enjoy the same conditions of access to and use of chemical monitoring data retrievable through the IPCHEM platform. The various IPCHEM User Groups are further described in Article 5.

Article 3. Roles and Responsibilities

Data Owners/ providers / controllers are responsible for making available their data via IPCHEM.

The Data Owner is responsible for the accuracy, integrity and quality of its own data. The Data Owner may nominate the Data Provider who on behalf of the Data Owner will be in charge of the collection, acquisition, production, management, quality control and/or publication and dissemination of data.

Data Owners/ Providers / Controllers should inform about and provide the JRC with the data and metadata of their data collections and keep this information updated.

Module Coordinators of IPCHEM actively identify new data collections, establish and maintain contact with Data Providers, implement the IPCHEM Data Policy, facilitate the communication between Data Providers and the JRC, promote standardisation of the data, cooperate among each other and with JRC to achieve interoperability among the IPCHEM thematic modules.

DG Environment as the Policy Lead of IPCHEM defines directions for IPCHEM development and jointly with the JRC as Scientific and Technical Lead decides on the creation of Thematic Modules and Project Groups under IPCHEM. In these tasks the Policy Lead is supported by its partners such as DG SANTE and DG RTD.

The Project Coordinator must ensure that the project-specific data access rules are agreed with all the Data Owners and Data Providers involved in the research project and that ethics approval is in place and allows the transfer of the data into IPCHEM at the specified access levels.

The JRC as Scientific and Technical Lead of IPCHEM develops, implements and maintains the technical infrastructure of IPCHEM, ensures a proper functioning of IPCHEM, ensures that the technical infrastructure corresponds to the agreed requirements and complies with the IPCHEM Data Policy, ensures communication with Users and Project groups and provides hosting facilities for data. The JRC further supports the Policy Lead by: exploring and promoting the progressive development of IPCHEM; advising on the technical feasibility and impacts on the IPCHEM platform of agreements reached with Data Providers; assessing the technical implications of alternative IPCHEM implementation scenarios and assessing the feasibility of alternative or additional sets of functionalities and their impact on the IPCHEM architecture. JRC also identifies new data collections that are relevant for IPCHEM and promotes IPCHEM to relevant stakeholders.

Users shall, where applicable, respect the licensing conditions and limitations of use imposed by applicable legislation (in particular data protection legislation) and by the Data Providers or Data Owners, which are shown on the IPCHEM platform, along with the metadata or elsewhere on the platform.

The European Commission shall make all reasonable efforts to ensure that the IPCHEM platform offers the necessary functionalities and qualities in terms of accessibility, security, stability, etc. The technical characteristics of the IPCHEM platform may be further described in additional documentation of the platform made available via the IPCHEM webpage, such as tutorials, provision of data and metadata templates.

Access to Chemical Monitoring Data Retrievable through the IPCHEM Platform

Article 4. Open Data Principles

- 1. By default, the chemical monitoring data retrievable through the IPCHEM platform shall be made available to all User Groups under the conditions of Free, Full, Open and Timely access according to the "European strategy for data" and the Open Data Directive.
- 2. The chemical monitoring data retrievable through the IPCHEM platform shall be made available to all User Groups as single measurement data unless one or several of the exceptions listed below in Article 6 apply, or subject to specific conditions deriving from those exceptions.
- 3. If single measurement data is not available, the data should be made available to all User Groups at the highest degree of detail possible, unless one or several of the exceptions listed below in Article 6 apply, or subject to specific conditions deriving from those exceptions.
- 4. The data shall be provided with all the necessary attributes to facilitate their interpretation and shall be accompanied by the metadata to make them usable and understandable by the user, unless one or several of the exceptions listed below in Article 6 apply, or subject to specific conditions deriving from those exceptions.

Article 5. IPCHEM User Groups

For the purposes of management of access to and use of the chemical monitoring data retrievable through the IPCHEM platform, IPCHEM Users are divided into four User Groups that can be granted different levels of accessibility to the data following the rules set out in Article 7 below:

- 1. European Commission Services and EU Agencies: all European Commission Services and all the European executive and decentralised Agencies.
- 2. EU National Bodies: EU Member States Competent Authorities, including Competent Authorities in countries from the European Free Trade Area and EU Candidate Countries. If the recipient is outside the European Economic Area (EEA), the transfer of personal data needs to ensure that the level of protection of natural persons guaranteed in EU data protection legislation is not undermined.
- 3. *General Public:* a generic user who does not belong to any of the other groups and accesses IPCHEM without authentication, including industry, scientific communities, international and non-governmental organisations.
- 4. Temporary project groups: if needed for a specific (research) project, a user group can be formed for a specified period of time, to allow data sharing for the project period. The data will be made available to a wider user group (as defined in groups 1,2,3 above) in agreement with the project team at the latest at the end of the project. For details see Article 11.

The JRC will by default have access to all data in order to execute its tasks as Scientific and Technical Lead of IPCHEM.

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⁶ ttps://ec.europa.eu/info/publications/communication-european-strategy-data_en

⁷ Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information PE/28/2019/REV/1; OJ L 172, 26.6.2019; http://data.europa.eu/eli/dir/2019/1024/oj

Article 6. Exceptions to Open Data Principles

- 1. As an exception to the Open Data Principles defined in Article 4 above, the Data Owner or Data Provider may impose to specific Users or User Groups exceptional accessibility regimes that restrict access to specifically identified chemical monitoring data.
- 2. Exceptional accessibility regimes can be imposed in the following cases, provided that they are based on legislation or regulatory sources or on contractual obligations:
 - a. Protection of personal data: Chemical monitoring data retrievable through the IPCHEM platform, may contain data relating to individuals who are identified or identifiable, directly or indirectly, and therefore those data are personal data⁸. The Data Provider or Data Owner bears the full responsibility for ensuring that the data supplied to IPCHEM are compliant with personal data protection rules. Data Providers or Data Owners are responsible to anonymise or pseudonymise information provided to IPCHEM. They commit themselves to notify to the IPCHEM team if they intend to provide pseudonymised (personal) data in order to allow following adequate procedures. Prior to rendering data sets public, data from which individuals can be directly or indirectly identifiable shall be aggregated in order to ensure that data are properly anonymised and therefore are not considered personal data in accordance with data protection legislation. Specific provisions related to personal data, including human biomonitoring data are described in Article 9.
 - b. Protection of licensing conditions, commercial interests and intellectual property rights: Data made available to IPCHEM by a Data Owner/Data Provider may have their own data access agreements and license conditions, which partly restricts how or when European Commission can make data available to others via IPCHEM, provided that the license conditions are not incompatible with the Open Data Principles and that they are accepted by the European Commission. The Data Provider or Data Owner has a responsibility to inform the JRC about such licensing conditions using Annex I. The Data Owner/Data Provider license conditions will be reported or linked in the corresponding Metadata page of the IPCHEM portal. The Data Provider or Data Owner has also the responsibility to clearly identify data considered commercially sensitive or covered by intellectual property rights that shall not be disclosed, and to communicate the relevant information to JRC who bears the responsibility of acting accordingly.
 - c. Protection of contractual obligations restricting access to data. The Data Provider or Data Owner is responsible for indicating precisely any specific contractual obligations and restrictions regarding data accessibility stipulated by them, and for communicating them to JRC who is responsible to handle such data accordingly.
- 3. In addition to the exceptions listed above, other restrictions or exceptions to the Open Data principles may also apply, as follows:

a) Protection of the public interest

Exceptions to the general Open Data Principles and their Exceptions may be imposed by binding rules, including international treaties, European Union law and national legislation for various reasons including protection of the public interest in security, defence and military matters, international relations, financial, monetary or economic policy of the European Union or the Member States, as well as protection of the privacy and integrity of individuals.

⁸ 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, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (Text with EEA relevance.) http://data.europa.eu/eli/reg/2018/1725/oj

b) Needs of court proceedings or legal advice

This type of restrictions encompass situations where data are used in cases adjudicated by courts or where legal advice referring to them is provided, and making them publicly available would adversely affect those procedures.

c) The purpose of inspections, investigations and audits

Similarly to point d. data can be used in other types of investigatory proceedings or audits and when their successful completion relies on non-availability of data to the public.

- d) Special rules for handling sensitive data in regulatory mechanisms that govern access to data of specific types, or data held by specific institutions
- 4. Notwithstanding the existence of exceptional accessibility regimes in the cases laid out in paragraph 2 and 3, data may still be disclosed or accessed when necessary to comply with a number of relevant pieces of applicable legislation, including but not limited to the following:

a) Regulation (EC) No 1049/2001 on public access to European Parliament, Council and Commission documents

The general Open Data Principles and their Exceptions (Articles 4 and 6) are without prejudice to the access to data that may be granted upon specific requests sent to the European Institutions under Regulation (EC) No 1049/2001⁹ on public access to documents. In such instances a case by case assessment of the specific request and accessibility of data will be performed by the European Institutions that received the request in accordance with the provisions of the Regulation and the exceptions to disclosure contained therein.

b) Legislation providing for data sharing among EU Commission, EU Agencies and Member States

The general Open Data Principles and their Exceptions (Articles 4 and 6) are without prejudice to cases where data are shared in a specific context such as a Scientific Opinion involving one or more different European Commission Services, EU Agencies or management of a crisis requiring data sharing between Member States, the European Commission and EU Agencies (e.g. the one foreseen in Article 55 of Regulation (EU) 178/2002)¹⁰.

Article 7. Imposition of Exceptional Accessibility Regimes

1. For the reasons listed in Article 6.2 and 6.3 above, the Data Owner or Data Provider can impose different exceptional accessibility regimes to different User Groups.

2. The exceptional accessibility regimes consists of the following:

- a. Providing access to aggregated data only;
- b. Providing access to filtered single measurement data only;
- c. Providing access to generalised single measurement data only;

⁹ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p.43

¹⁰ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24, as last amended

- d. Restricting access to data for a limited time period (i.e. embargo period);
- e. Providing metadata only;
- f. Providing access to single measurement data, subject to conditions, obligations and safeguards to comply with data protection legislation.
- g. Using a combination of the above (i.e. combination of (a) to (e)).
- 3. Even if exceptional accessibility regimes are imposed, metadata shall always remain retrievable through the IPCHEM platform for all User Groups.
- 4. Amongst the possible exceptional accessibility regimes, the European Commission and Agencies shall always be granted the one providing the highest level of detail possible, and at the very least they shall have access to aggregated data.
- 5. For data hosted in IPCHEM, the JRC will always have access to all the data provided, including data at single measurement level. JRC needs access to the data in order to execute tasks like data integration and IPCHEM maintenance. Further, JRC is allowed to use data for scientific analysis supporting policy making in the area of impact of chemicals on the environment and on human health.
- 6. Whenever a specific exceptional accessibility regime has to be imposed, it shall be indicated and communicated by the Data Provider or Data Owner to JRC before submitting data to IPCHEM using the supporting documentation specified in the Annex I and indicating the accessibility regime for each category of data and User Group.
- 7. If the specific exceptional accessibility regime contains an embargo period, the Data Provider or Data Owner is responsible for clearly formulating the reasons for such an embargo, the embargo criteria and duration, the accessibility regimes to be applied once the embargo is over, and for communicating them to JRC who is then responsible of handling the data accordingly.

Article 8. IPCHEM Data Accessibility

- The chemical monitoring data retrievable through the IPCHEM platform, whenever applicable and
 possible, shall be made available by the Data Provider or Data Owner in an accepted, platformindependent, machine-readable format via proper interfaces that will enable establishing remote access
 to data managed at source.
- Access to chemical monitoring data retrievable through the IPCHEM platform may be subject to registration and authentication when they are subject to specific rules of a Project Group (as defined in Article 5 and 11) or when different Exceptional Accessibility Regimes are imposed to different User Groups. The Authentication Service of the European Commission (EU Login) is used to control the Users' registration and authentication.

Article 9: Specific provisions for human biomonitoring data

In the Human Biomonitoring Module, IPCHEM includes occurrence data of chemicals in human samples. In most cases, human biomonitoring (HBM) data can be (sufficiently) aggregated so that they can be considered anonymous and are not considered personal data anymore. However, HBM data can also be provided as pseudonymised individual level single measurement data, which have to be considered "health data" and thus fall under the category of special categories of personal data according to GDPR/EUDPR.

The processing of HBM data by data owners, including the transfer to JRC must comply with applicable data protection legislation. In particular:

In the case of individual level pseudonymised HBM data, JRC will proceed as joint controller with the supplying data controller (e.g. HBM4EU consortium partner). The supplying data controller is responsible for the safekeeping of the key that could allow the re-identification of the individuals. JRC as receiving controller does not receive this key.

Joint controllership agreements according to Article 28 (Regulation (EU) 2018/1725) will be established between the JRC 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.

JRC accepts only data which are fully compliant with national ethics and legal requirements for hosting in IPCHEM hosting facility. It is the full responsibility of the data owner/provider/supplying controller to be compliant with these requirements and restrictions.

When Data Providers plan to provide pseudonymised data to IPCHEM from the beginning of the study, data subjects shall be directly asked whether they consent to share data at EU level with EU institutions.

It is the full responsibility of the supplying data controller to ensure that the data subject's consent with regard to collection by the data owner/provider/controller, transfer to and further processing by the JRC complies with the requirements of Art. 7 and recital 26 of the EUDPR; and Art. 7 and recital 42 of the GDPR and the EUDPR. Accordingly, the supplying data controller shall ensure that the data subject is aware of the identity of JRC as joint controller for further processing and of the purposes, and gives explicitly consent to it.

For data from existing studies that were not explicitly asking consent to share pseudonymised data at EU level, the controller providing the data would need to get consent from the data subject to provide data to IPCHEM or instead should only share aggregated / anonymised data that are not considered to be personal data in accordance with data protection legislation.

JRC can accept to host in IPCHEM hosting facility data which are subject to 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 and applicable to different categories of users other than JRC. It is the full responsibility of the data owner/provider/controller to make the JRC fully aware of the exceptional accessibility regimes. The data owner/provider/controller and the JRC will conclude a specific agreement setting out the practical arrangements to ensure compliance with such regime.

Notwithstanding the existence of exceptional accessibility regimes for different categories of users, such regimes shall not apply to the JRC. Accordingly, the JRC will have access to all the data hosted at IPCHEM hosting facilities and may use such data exclusively in the context of JRC's mission of scientific research in support of policy making for specific purposes to be agreed in the joint controllership agreement. It is the full responsibility of the supplying data controller to ensure that the data hosted in the IPCHEM hosting facility is free from any exceptional accessibility regime that may limit access and use by JRC.

Access to pseudonymised data hosted in IPCHEM will always be controlled and restricted to the joint controllers, as well as to data processors. The HBM data supplying controller directly uploads the data in the hosting facilities and manages the access of authorised users.

Access to pseudonymised data hosted in IPCHEM may also be granted by JRC to third parties as recipient, for further processing as controller or processors, if all of the following requirements are fulfilled:

- 1 The supplying data controller has signed a specific agreement with the receiving controller or processor.
- 2 In accordance with Art. 9 EUDPR, the JRC establishes that:
 - a) The data are necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the recipient, or

- b) It is necessary to have the data transmitted for a specific purpose in the public interest and the controller that provided the data and the JRC, where there is any reason to assume that the data subject's legitimate interest might be prejudiced, establish that it is proportionate to transmit the personal data for that specific purpose after having demonstrably weighed the various competing interests.
- The supplying data controller warrants and undertakes that the consent given by the data subjects covers the sharing with these third parties, and in particular that the data subjects are aware at least of the identity of the recipient and the purposes of further processing by it, and have given explicit consent to such transmission and further processing. The controller providing the data will need to be able to provide proof of the compatibility upon request. Details will be regulated in specific data transfer agreements and joint controllership agreements. The JRC will set up access accounts, based on EU Login, for both the data controller and data processor for uploading and accessing to pseudonymised data.

Relevant safeguards are put in place in the IPCHEM Portal and IPCHEM Share subsystem. They are hosted on dedicated servers of the corporate JRC Information System Hosting environment observing DG DIGIT's security standards. Pseudonymised HBM data will be hosted in the IPCHEM Share subsystem observing strict security measures including strict access control and encryption. The supplying data controller has to ensure that the key for re-identification is not transferred and kept safe.

Use of IPCHEM for projects on chemical monitoring data

Article 10. Projects on chemical monitoring data

IPCHEM can be used as a platform for data collection and exchange within research projects with the objective to make the chemical monitoring data collected or produced within the projects available to the regulatory authorities and public as soon as possible and to ensure continuity in data accessibility. In this context the application of the rules described in Articles 4-7 above can be temporarily suspended as described in Article 11 below.

Article 11. Project Groups and data accessibility rules

If a research project generates, collects or analyses chemical monitoring data, a Project Group can be created under IPCHEM based on the request of a Project Coordinator. A Project Group consists of users nominated by the Project Coordinator through an agreement or formal nomination procedure and who have specific rights to access and use the chemical monitoring data that are generated, collected or analysed in the context of the specific research project. The creation of a Project Group under IPCHEM has to be agreed by the IPCHEM Policy Lead.

If such a Project Group is created, the project coordinator must ensure that the project-specific data access rules are agreed with all the Data Owners / Providers / Controllers involved in the Project Group. Data Owners being part of the Project Group can decide to share data with the members of the Project Group only and not provide any data to IPCHEM User Groups. Exceptionally, IPCHEM User Groups can be refused access to metadata as well. Module Coordinators and JRC however maintain the right to review the work and progress achieved within the Project Group to ensure compliance with the scope of IPCHEM, the IPCHEM Data Policy and any possible agreements with the Project Group.

These extraordinary project-specific accessibility rules can only last temporarily as long as the specific Project Group exists. Upon the dissolution of the specific Project Group, the data generated, collected or analysed in the course of the Project will have to be made accessible to IPCHEM User Groups according to the Open Data

Principles and the Exceptional Accessibility Regimes described in Articles 4-7 above. The conditions of the access to the data to the IPCHEM User Groups will be decided by the Data Owners or Data Providers being members of the Project Group.

In any event, the Data Owners and Data Providers should aim at making their chemical monitoring data available to the European Commission and EU Agencies as soon as practically possible, even before the dissolution of their specific Project Group.

Use of data retrieved via IPCHEM

Article 12. Conditions of Data Use

- 1. The user of the chemical monitoring data retrievable through the IPCHEM platform is entitled to such acts as reproduction, communication to the public, adaptation, modification, combination with other data and information, distribution of the data with or without any modifications by the user, extraction and reutilisation, as well as any combinations of such acts, for both non-commercial and commercial purposes, provided that such uses do not circumvent the Exceptional Accessibility Regimes granted by the Data Owner or Data Provider and are not prohibited or limited by the applicable licensing conditions imposed by the Data Owner or Data Provider. For instance, if a user has accessed data through the IPCHEM platform at a higher degree of detail than others as a result of the existence of Exceptional Accessibility Regimes or the existence of a Project Group, it shall not use data in any manner that would in effect disclose these details to users not entitled to get such access under the accessibility rules defined by the Data Owner or Data Provider.
- 2. The user shall acknowledge the source of chemical monitoring data retrievable through the IPCHEM platform whenever such data are used, citing at least:
 - The title of the original data collection,
 - The Data Owner and /or Data Provider (name of the institution),
 - The IPCHEM platform as the source from where the data were retrieved and the link to the data collection in IPCHEM.

Where the data retrieved is personal data, the user shall comply with the obligations imposed by applicable data protection legislation. In particular, the data shall be used exclusively for scientific research purposes or other purposes compatible with them.

Article 13. Warranties and Limitations of liability

- 1. The chemical monitoring data retrievable through the IPCHEM platform is provided "as is" without warranty of any kind, either expressed or implied, including, but not limited to, any implied warranty against infringement of third parties property rights (subject to article 13.5), or merchantability, integration, satisfactory quality and fitness for a particular purpose.
- Data Providers, Data Owners and Module Coordinators have no obligation to provide technical support
 or remedies to IPCHEM users for the chemical monitoring data retrievable through the IPCHEM platform.
 In addition they do not represent or warrant that their data will be error free or uninterrupted, or that all

- non-conformities can or will be corrected, or that any data are accurate or complete, or that they are of a satisfactory technical or scientific quality.
- 3. The European Commission, Data Providers, Data Owners and Module Coordinators shall not be held liable for any direct or indirect, incidental, consequential or other damages, including but not limited to the loss of data, loss of profits, or any other financial loss arising from the use of the chemical monitoring data retrievable through the IPCHEM platform, or inability to use them properly.
- 4. Data Providers and Data Owners shall keep the European Commission harmless against any claim by a third party alleging that the publication of the chemical monitoring data on the IPCHEM platform infringes their own intellectual property rights.
- 5. Additional disclaimers of liability may apply, as the case may be, according to the licensing conditions imposed by the Data Providers and Data Owners.

Making chemical monitoring data available via IPCHEM

Article 14. Procedure for making chemical monitoring data available via IPCHEM

- 1. Data Provider or Data Owner, interested by making their data available via IPCHEM, shall first complete the "IPCHEM participation form" (as attached in Annex I or as adapted, if needed, by the European Commission) and shall deliver it to JRC either directly or via the Module Coordinator. In this form the Data Provider or Data Owner will provide information about themselves (i.e. their organisation or company), their data collection and will specify the data access conditions for different IPCHEM User Groups. Data Owners or Data Providers shall complete one form per data collection.
- 2. The interested Data Provider or Data Owner will then be asked by the Module Coordinator or JRC to provide a standard set of metadata describing their data collection(s), along with some additional technical information. This technical information will be used to understand how best to link/integrate the data provided in the IPCHEM platform and to identify the best solution for accessing or hosting the data in IPCHEM.
- 3. JRC will then link/integrate the data into the IPCHEM platform. The Data Owner or Data Provider may be contacted by JRC should there be a need to clarify any relevant technical issues.
- 4. The Data Provider or Data Owner will then be asked to check their data in IPCHEM to make sure that they are presented according to their expectations and data accessibility requirements. A preview of this data under IPCHEM will be made accessible to the Data Provider or Data Owner so that, if required, they can request changes and improvements to the specific pages created in IPCHEM that present their data collection. Should there be no response from the Data Provider or Data Owner within three weeks from the request, the specific data collection pages shall be considered as approved for publication in IPCHEM.
- 5. On the basis of the feedback received from the Data Provider or the Data Owner, JRC will then revise the data collection pages accordingly and publish the specific data collection via IPCHEM.

Article 15. Registration of a Project Group under IPCHEM

1. A project coordinator, interested of creating a Project Group under IPCHEM, shall contact JRC with the request to create a Project Group. When doing so, the project coordinator shall provide information about

- the project and the chemical monitoring data that will be generated, collected or analysed within the project that are relevant to IPCHEM.
- 2. The JRC after consultation with DG Environment as the Policy Lead will then communicate to the interested project coordinator the acceptance or rejection of his/her request.
- 3. If the request of creating a specific Project Group is accepted, the JRC will approach the interested project coordinator to agree on the technical aspects including the nomination of the users of the specific Project Group and the specification of their accessibility rights.

Article 16. Terminating availability of chemical monitoring via IPCHEM

When a Data Owner or Data Provider wishes to terminate the availability of their data via the IPCHEM
platform, he/she will inform the JRC in writing. The data will then be made inaccessible via the IPCHEM
platform as soon as reasonably possible.

Implementation and review of the IPCHEM Data Policy

Article 17. Roles and Responsibilities in the implementation of the IPCHEM Data Policy

- 1. The implementation of the IPCHEM Data Policy shall be under the responsibility of the JRC as Scientific and Technical Lead and the Module Coordinators.
- 2. Oversight and monitoring of the implementation of the IPCHEM Data Policy shall be the responsibility of the DG Environment as the Policy Lead.
- 3. The Module Coordinators and the Scientific and Technical Lead will provide the necessary assistance to the Policy Lead in the oversight and monitoring of the implementation of this Data Policy.

Article 18. Future Review of the IPCHEM Data Policy

- 1. This IPCHEM Data Policy shall be reviewed and updated as necessary every 3 years.
- 2. The Policy Lead in collaboration with the Scientific and Technical Lead shall organise the procedure regarding future amendments of the IPCHEM Data Policy.

Miscellaneous

Article 19. Applicable law and jurisdiction

- 1. This policy and the contractual relations based upon this policy will be governed by European Union legislation, complemented, where necessary, by Belgian law.
- 2. Any dispute which cannot be settled amicably shall be submitted to the exclusive jurisdiction of the Brussels courts.

Annex I

IPCHEM Participation Form

To be completed by Data Providers or Data Owners for making their data accessible via IPCHEM (the Information Platform for Chemical Monitoring)

1. Purpose of this form

Using this form, the Data Collection Contact Point, representing the Data Owners/Providers/Controllers, shall communicate the conditions under which they agree to make their chemical monitoring data, together with the associated metadata, accessible to the Users of the Information Platform for Chemical Monitoring (IPCHEM).

The Data Contact Point is requested to complete one form per data collection.

Guidelines for the participation in IPCHEM along with explanation of any terms used can be found in the "IPCHEM Data Policy" and other documentation available on the IPCHEM webpage¹¹.

This form is to be completed by the Data Collection Contact Point and sent by email to the IPCHEM Team at: JRC-IPCHEM-SUPPORT@ec.europa.eu

2. General information

Acronym of the data collection	
Full name of the data collection	
Name of the Data Provider organisation	
Role of data contact point	☐ Data Controller / ☐ Data Owner / ☐ Data Provider
Name of Contact Point	
Telephone	
E-mail	
Address of Contact Point organisation	
Name of the Data Owner organisation	
(if different from the Data Provider)	
Address of Data Owner organisation	
(if different from the Data Provider)	
Name of the Data Controller organisation	
(if different from the Data Provider)	
Address of Data Controller organisation	
(if different from the Data Provider)	

Together with this Participation Form, please provide a metadata description of your data collection using the metadata template available for download in the IPCHEM Portal¹².

The metadata should be completed by the Data Provider/Owner and sent by email to the IPCHEM team at: JRC-IPCHEM-SUPPORT@ec.europa.eu

¹¹ https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html#bepart

¹² https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/documents/Metadata template.xlsx

3. Data access conditions

3.1 Data access conditions for data in the IPCHEM modules 1, 3 and 4 (Environmental, Food and Feed and Products and Indoor Air monitoring data)

Data Contact Points are requested to complete the table below in order to indicate the conditions under which their data can be made accessible to IPCHEM Users.

Level of data to which users have access	IPCHEM User Groups			
users mave decess	1. JRC IPCHEM team	2. EU Commission and Agencies	3. EU National Bodies	4. General Public
a. Metadata	yes	yes	yes	yes
b. Aggregated data	yes	yes	yes/no/not applicable	yes/no/not applicable
			(select an option)	(select an option)
c. Filtered or generalised	yes	yes/no/not applicable	yes/no/not applicable	yes/no/not applicable
single measurement data		(select an option)	(select an option)	(select an option)
d. Single measurement	yes	yes/no/not applicable	yes/no/not applicable	yes/no/not applicable
data		(select an option)	(select an option)	(select an option)

Please select an option (yes/no/not applicable) in the relevant fields.

3.2 Data access conditions for IPCHEM module 2 (Human Biomonitoring data)

Human Biomonitoring data submitted to the JRC IPCHEM team can be anonymised or pseudonymised.

Aggregated data and anonymised single measurement data can be shared via the IPCHEM portal and can be made available to different user groups and even to the public.

Pseudonymised single measurement data can be shared only via the IPCHEM Share subsystem under additional Data Transfer Agreement and Joint Controllership Agreement. Based on its mandate, the JRC needs to be co-controller in order to host such data and will have access to the data by default. JRC may use such data exclusively for the purpose of scientific research in support of policy making, within the scope agreed in the Joint Controllership Agreement. The controller providing the data is responsible for ensuring that the consent given by the data subject covers the sharing with JRC and if applicable further third parties (as outlined in Article 9 of the IPCHEM data policy).

Data Contact Points are requested to complete the table below in order to indicate the conditions under which their data can be made accessible to IPCHEM Users.

Level of data to which users have access	IPCHEM User Groups			
	1. JRC IPCHEM team	2. EU Commission and Agencies	3. EU National Bodies	4. General Public
a. Metadata	yes	yes	yes	yes
b. Aggregated data	yes	yes	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)
c. Anonymised single measurement data	yes	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)
d. Pseudonymised single measurement data	yes (joint controller)	Only under specific data transfer agreements	Only under specific data transfer agreements	no

3.3 Additional licensing conditions

For any data set, Data Contact Points have the possibility to ask that additional licensing conditions apply to their data, provided that such conditions do not conflict with the Open Data Principles, as they are defined in the Data Policy available here. In such case, the licensing conditions or a reference thereto will be displayed in the metadata section of the relevant datasets.

Licen	sing conditio	ns (if applicable):		
Please	select an o _l	otion:		
Yes	- 1	No	If yes, please specify by reference to a standard open licence e.g. Creative Commons or provide text:	
In case	e of aggrega	ted data, please specify	y if data are provided as:	
	A. Spatially aggregated (the summary statistics represent aggregation of measurements a level, NUTS 1,2,3 Level, City level etc.)			
	Please pro	vide details:		
	by months	s, years, etc.)	mmary statistics represent measurements of a sampling aggregated	
	Please pro	vide details:		
	C. Spatiall	y/temporally aggregate	ed (the combination of a and b)	
	Please pro	vide details:		
	<i>D. Semant</i> (humans/l	,	summary statistics refer to groups of class of targeted population	
	Please pro	vide details:		
In case	e of filtered	or generalised single m	easurement data, please specify if data are provided as:	
			butes that directly or indirectly violate the privacy, such as specific ial coordinates, the identity of the target population, etc.)	
	Please pro	vide details:		
	representi		nent of the specific location of the samplings with coordinates ich as the centroid of the town centre, or by removing the number latitude coordinates)	
	Please pro	vide details:		

Signing this form the Data Owner/Data Provider agrees to make their data collection(s) accessible the IPCHEM platform and accepts the IPCHEM Data Policy.	rough
If the Data Provider is different from the Data Owner, the Data Provider confirms that he entitled to agree to this document concerning the data collection of the Data Owner.	she is
The data owner/data provider agrees to make the metadata and thus also his/her name and condetails publicly available.	ontact
Date	
Place	
Signature of the ☐ Data Owner/☐ Data Provider / ☐ Data Controller	
Name and first name of signatory:	
Title/function of signatory:	