

# **DATA ACT: ACCESS TO DATA FOR SCIENTIFIC RESEARCH OF SUBSTANTIAL PUBLIC INTEREST**

The German government proposes access by public research institutions to private sector data in the substantial public interest in order to raise the innovation potential of data in science. Harmonized data access for research must be specific, proportionate and in compliance with data protection law, in particular through close proximity to a research organization, independence from commercial interests, protection of trade secrets and restriction to research projects of substantial public interest and cross-border relevance. Existing and future sector-specific regulations, such as in the area of health data, shall be respected and their primary regulations shall not be undermined. These primary access regulations must prevail over the Data Act.

\*\*\*Not final, subject to further discussion and change, also from Germany.\*\*\*

Any processing of personal data in connection with the rights and obligations laid down in this Regulation and this Chapter must comply with all conditions and rules provided by data protection legislation, including but not limited to the need for a valid legal basis under Article 6 of Regulation (EU) 2016/679, where relevant the conditions of Article 9 of Regulation (EU) 2016/679 and Article 5(3) of Directive (EU) 2002/58. Those businesses and researchers should pay particular attention to the protection of personal data and ensure that any processing of personal data complies with Regulation (EU) 2016/679. Providers should anonymise or pseudonymise personal data except in those cases that would render impossible the research purpose pursued, subject to compliance with all conditions and rules provided by data protection legislation.

This Chapter does not create or recognise a legal basis in the sense of Article 6(1)(c) and/or 6(3) of Regulation (EU) 2016/679.

Sector-specific provisions for sharing, access and use of data for scientific research should not be circumvented by the more general provisions of the Data Act. Otherwise, the more specific requirements of the sector-specific regulations could be bypassed. For the Data Act, a clarification was therefore included in Article 22a (3) that Chapter Va is inapplicable where such requirements exist. This is intended to ensure legal certainty and clarity through a transparent and easy-to-implement demarcation between the provision for accessing data in Chapter Va of this regulation and prevailing provisions in sector specific legislations, such as the planned Regulation for a European Health Data Space.

## **CHAPTER Va**

# **ACCESS TO DATA FOR SCIENTIFIC RESEARCH OF SUBSTANTIAL PUBLIC INTEREST**

*Art. 22a*

*obligation to make data available for scientific research*

1. Upon request a data holder shall make data, as defined in Art. 2 (1) to 2 (1af) and as defined by recital 14a, available for scientific research. A request for data may only be submitted by a researcher who is affiliated to a research organisation within the meaning of Commission recommendation C(2008)1329 on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations and
  - (a) that is established in the Union, provided that the majority of its governing body is established in the Union or Union member states and that it receives the majority of its funding from within the Union or Union member states and
  - (b) a study or research project that is of substantial public interest and addresses cross-border aspects of
    - i. Agriculture, forestry and rural areas
    - ii. Bio economy
    - iii. Crisis and disaster management
    - iv. Energy
    - v. Environment
    - vi. Food security
    - vii. Frontier research
    - viii. Health
    - ix. Information and communication technologies
    - x. Migration
    - xi. Oceans and seas
    - xii. Public security
    - xiii. Employment, Social and Humanitarian affairs, Inclusion, Socio-economic Development
    - xiv. Space
    - xv. Transport and mobility
    - xvi. Climate.
2. The obligations of this Chapter shall not apply to data holders which are businesses that qualify as micro or small enterprises, as defined in Article 2 of the Annex to Recommendation 2003/361/EC, provided those enterprises do not have partner enterprises or linked enterprises as defined in Article 3 of the Annex to Recommendation 2003/361/EC which do not qualify as a micro or small enterprise. The same shall apply to data holders enterprises that qualify as medium-sized enterprises as defined in that

same Recommendation, for either medium-sized enterprises that meet the threshold of that category for less than two years or that where it concerns products that a medium-sized enterprise has been placed on the market for less than two years.

3. Where Union law or national acts based on Union law establish more specific rules for certain categories of data concerning the sharing, access and use of data for scientific research, this Chapter shall not apply to these categories of data. Member State law may allow additional entitlements to access data for research purposes.
4. The Commission is empowered to adopt delegated acts in accordance with Article 38 in order to amend point (b) of Article 22a (1) by adding new cross-border subjects of substantial public interest that can be addressed by research projects in order to reflect scientific developments.

*Art. 22b*  
*access request to data*

1. When requesting data pursuant to Article 22a the researcher shall:
  - (a) provide detailed information on the specific scientific research project concerning the data request;
  - (b) specify which data are required and indicate access criteria, such as the location, duration and groups of persons involved;
  - (c) demonstrate that access to the data requested is necessary for and proportionate to the purposes of the specific scientific research project and that the expected results of that research will contribute to the purposes laid down in Article 22a (1);
  - (d) disclose all funding of the research project;
  - (e) demonstrate that the research organisation fulfils the requirements of Art. 2 (1) of Directive (EU) 2019/790 and that data will be processed by the research organisation or to a data intermediary acting on their behalf;
  - (f) demonstrate the affiliation to the research organisation and their full independence from commercial interests;
  - (g) ensure that all specific necessary measures, including technical and organisational measures, are taken to preserve the confidentiality of data and its trade secrets, in particular with respect to the use of data in research consortiums.
2. disclose the parties that participate within the research project and will have access to the data.
3. A request for data made pursuant to paragraph 1 shall:
  - (a) be expressed in clear, concise and plain language understandable to the data holder;

- (b) respect the legitimate aims of the data holder considering the protection of trade secrets and the cost and effort required to make the data available;
- (c) in case personal data are requested, the request should justify the need for including personal data and set out the technical and organisational measures that will be taken to protect the data.

*Art. 22c*

*Involving a data intermediation service*

1. The request for data according to Article 22a can be submitted on behalf of a researcher by a provider of data intermediation services set out in Chapter III of Regulation (EU) 2022/868 (Data Governance Act). Compliance to the rules for data intermediation services can be demonstrated by a confirmation as laid down in Article 11(9) of Regulation (EU) 2022/868.
2. The data holder may choose to either make data available directly to the researcher or via a data intermediation service. If the data holder chooses to make data available via a data intermediation service, the use of a data intermediation service becomes mandatory.
3. Data intermediation services shall comply with all obligations laid down in Article 22b. The provider of the data intermediation service has to ensure that it has the capacity to preserve the specific data protection, security and confidentiality requirements corresponding to each request. The appropriate technical and organisational measures taken to this end have to be laid down in the request.
4. The research organisation according to Article 22a (1) (a) shall bear the costs incurred for involving a data intermediation service.

*Art. 22d*

*obligations of the researcher*

1. The researcher having received data pursuant to a request under Article 22a shall:
  - (a) only use the data for the specific scientific research project for which they were requested;
  - (b) preserve the confidentiality of trade secrets and has to ensure that the published data does not allow any conclusions on single companies;
  - (c) make the research results publicly available free of charge, within a reasonable period of time after the completion of the research project taking into account the rights and interests of the recipients of the service concerned;
  - (d) not make the data available to a third party.
2. The data may be retained for the purposes of the research project, including for the verification of research results. The researcher shall erase the data as soon as they are no longer necessary for purposes of sentence 1 and inform the data holder without undue delay that the data have been erased.

*Art. 22 da*

*Obligations of the data holder*

Where the dataset requested includes personal data, the data holder shall properly anonymise the data, unless the compliance with the request to make data available to researcher requires the disclosure of personal data,. In that case the data holder shall pseudonymise the data, insofar as the request can be fulfilled with pseudonymised data.

*Art. 22e*

*rights of the data holder and compensation*

1. The data holder may decline or seek the modification of the request within 30 calendar days following the receipt of a request for the data, on either of the following grounds:
  - (a) the data holder does not have control over the data requested;
  - (b) the request does not meet the conditions laid down in Art. 22a (1) and Art. 22b;
  - (c) the data holder has already fully or in part made the requested data publicly available.
  - (d) the requested data has been substantially modified by the company and cannot be seen as data in raw form or prepared data as defined in Rec. 14 (1).
3. Disclosure of trade secrets or alleged trade secrets to the researcher shall only be required to the extent that it is strictly necessary to achieve the purpose of the request. In such a case, the researcher shall take appropriate measures to preserve the confidentiality of those trade secrets.
4. Compensation for the data holder for making data available shall not exceed the technical and organisational costs incurred to comply with the request including, where necessary, the costs of anonymization and of technical adaptation, plus a reasonable margin. Upon request of the research organisation requesting the data, the data holder shall provide information on the basis for the calculation of the costs and the reasonable margin.

*Art. 22g*

*Monitoring and Enforcement*

1. The designated competent authority as defined in Chapter IX is responsible for monitoring the implementation and the enforcement of the conditions set out in this Chapter.
2. The researcher must report any data requests submitted under Chapter Va to the competent authority, who retains a record of all data requests submitted in the Member State.