



EUROPEAN HEALTH AND DIGITAL EXECUTIVE
AGENCY (HADEA)

Brussels

**HADEA'S
RULES OF PROCEDURE
FOR THE APPLICATION OF REGULATION (EC) NO 1049/2001 OF THE EUROPEAN
PARLIAMENT AND OF THE
COUNCIL REGARDING PUBLIC ACCESS TO EUROPEAN PARLIAMENT, COUNCIL AND
COMMISSION DOCUMENTS**

THE STEERING COMMITTEE OF THE EUROPEAN HEALTH AND DIGITAL
EXECUTIVE AGENCY (HADEA)

Having regard to Commission Implementing Decision (EU) 2021/173 of 12 February 2021 establishing the European Health and Digital Executive Agency (hereafter referred to as “the Agency”)¹

Having regard to Commission Decision of 12.2.2021 delegating powers to the European Health and Digital Executive Agency with a view to the performance of tasks linked to the implementation of Union programmes in the field of EU4Health, Single Market, Research and Innovation, Digital Europe, Connecting Europe Facility – Digital, comprising, in particular, implementation of appropriations entered in the general budget of the Union HaDEA Act of delegation and annex²,

Having regard to Council Regulation (EC) No 58/2003 of 19 December 2002 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes, in particular article 23(1) thereof, pursuant to which an executive agency shall be subject to Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 on public access to European Parliament, Council and Commission documents when it receives a request for access to a document in its possession³,

Having regard to the Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents,

Whereas in accordance with Article 23 of the Council Regulation (EC) No 58/2003 of 19

¹ OJ L 50, 15.2.2021 p. 9-28.

² C(2021) 948 final.

³ OJ L 11, 16.1.2003, p. 1–8.

December 2002 and to Article 14 of the Commission Decision of 12 February 2021, the present rules of procedure shall be adopted by the Steering Committee.

HAS ADOPTED the following rules:

Article 1 *Beneficiaries*

Citizens of the Union and natural or legal persons residing or having their registered office in a Member State may exercise their right of access to the Agency documents under Article 15(3) of the Treaty on the Functioning of the European Union and Article 2(1) of Regulation (EC) No 1049/2001 in accordance with these detailed rules. This right of access concerns documents held by the Agency, that is to say, documents drawn up or received by it and in its possession.

Pursuant to Article 2(2) of Regulation (EC) No 1049/2001, natural persons not residing in a Member State and legal persons not having their registered office in one of the Member States may enjoy the right of access to Agency documents on the same terms as the beneficiaries referred to in Article 15(3) of the Treaty on the Functioning of the European Union.

Article 2 *Access applications*

All applications for access to a document shall be sent by mail or through other electronic means to the Agency. The addresses to which applications are to be sent and, where available, a description of other electronic means shall be published on the website of the Agency.

The Agency shall answer initial and confirmatory access applications within fifteen working days from the date of registration of the application. In the case of complex or bulky applications, the deadline may be extended by fifteen working days. Reasons must be given for any extension of the deadline and it must be notified to the applicant beforehand.

If an application is imprecise, as referred to in Article 6(2) of Regulation (EC) No 1049/2001, the Agency shall invite the applicant to provide additional information making it possible to identify the documents requested. In this case, the deadline for reply shall run only from the time when the Agency has this information.

Any decision which is even partly negative shall state the reason for the refusal based on one of the exceptions listed in Article 4 of Regulation (EC) No 1049/2001 and shall inform the applicant of the remedies available to him.

Article 3 *Treatment of initial applications*

Without prejudice to Article 9 of these Rules, as soon as the application is registered, an acknowledgement of receipt shall be sent to the applicant, unless the documentation requested can be sent by return.

The acknowledgement of receipt and the reply shall be sent in writing, by electronic means.

The applicant shall be informed of the response to his application within fifteen (15) working days from the date of registration of the application.

Any answer which is even partly negative shall be signed by the Director of the Agency and shall inform the applicant of the right of the applicant to submit, within fifteen working days from receipt of the answer, a confirmatory application to the Director of the Agency.

Failure by the Agency to reply within the prescribed time limit shall entitle the applicant to make a confirmatory application.

Article 4 *Treatment of confirmatory applications*

Decisions on confirmatory applications shall be taken by the Director of the Agency within fifteen working days from receipt of the request. Such decisions shall be notified to the applicant in writing, where appropriate by electronic means.

In case the initial refusal to grant access is confirmed, wholly or in part, the Director will inform the applicant of the right of the applicant to lodge a complaint with the European Ombudsman or to bring an action before the General Court under the conditions laid down in Articles 228(1) and 263(3) of the Treaty on the Functioning of the European Union.

Failure by the Agency to reply within the prescribed time limit shall be considered as a negative reply and entitle the applicant to lodge a complaint with the European Ombudsman or to bring an action before the General Court under the conditions laid down in Articles 228(1) and 263(3) of the Treaty on the Functioning of the European Union.

Article 5 *Consultations*

1. Where the Agency receives an application for access to a document which it holds and which originates from a third party, the Agency shall check whether one of the exceptions provided for by Article 4 of Regulation (EC) No 1049/2001 applies. If the document requested is classified under the Agency's security rules, Article 6 of these rules shall apply.
2. If, after examination, the Agency considers that access to the document requested must be refused under one of the exceptions provided for by Article 4 of Regulation (EC) No 1049/2001, the negative answer shall be sent to the applicant without consultation of the third-party author.
3. The Agency shall grant the application without consulting the third-party author where:
 - a. the document requested has already been disclosed either by its author or under the Regulation or similar provisions;

- b. the document requested does not originate from a Member State and it is obvious that the disclosure, or partial disclosure, of its contents would not affect one of the interests referred to in Article 4 of Regulation (EC) No 1049/2001.
4. In all the other cases, the third-party author shall be consulted. In particular, if the application for access concerns a document originating from a Member State, the Agency shall consult that Member State.
5. The third-party author consulted shall have a deadline for reply which shall be no shorter than five working days and must enable the Agency to abide by its own deadlines for reply. In the absence of an answer within the prescribed period, or if the third party is untraceable or not identifiable, the Agency shall decide in accordance with the rules on exceptions in Article 4 of Regulation (EC) No 1049/2001, taking into account the legitimate interests of the third party on the basis of the information at its disposal.
6. If the Agency intends to give access to a document against the explicit opinion of the author, it shall inform the author of its intention to disclose the document after a ten-working day period and shall draw the attention of the author to the remedies available to oppose disclosure.
7. Where a Member State receives an application for access to a document originating from the Agency, it may, for the purposes of consultation, contact the Director, who shall reply to the consultation.

Article 6

Treatment of applications for access to classified documents

Where an application for access concerns a document classified under the Agency's security rules, it shall be handled by staff members entitled to acquaint themselves with the document.

Where the Agency decides to refuse access to all or part of a classified document, it shall give reasons for its decision on the basis of the exceptions listed in Article 4 of Regulation (EC) No 1049/2001 in a manner which does not harm the interests protected under this Article.

If it proves that access to a classified document cannot be refused on the basis of these exceptions, the staff member handling the application shall ensure that the document is declassified before sending it to the applicant.

If the requested document is a sensitive document as defined in Article 9(1) of Regulation (EC) No 1049/2001, shall be released only with the consent of the originating authority.

Article 7

Exercise of the right of access

The applicant shall receive copies of the documents to which access has been granted. These copies shall be supplied in an existing version and format, including, where available, electronic copies, taking into account the applicant's preference, where

appropriate. If documents are voluminous or difficult to handle, the applicant may be invited to consult the documents on the spot. This consultation shall be free of charge.

If the document has been published, the answer shall consist of the publication references and/or the place where the document is available and, where appropriate, of its web address on the Agency's website.

If the volume of the documents requested exceeds twenty pages, the applicant may be charged a fee of EUR 0.10 per page plus carriage costs. The charges for other media shall be decided on a case by case basis but shall not exceed a reasonable amount.

Article 8

Measures facilitating access to the documents

1. In order to make citizen's rights deriving from Regulation (EC) No 1049/2001 effective, the Agency shall set up a publicly accessible register of documents held by the Agency, in particular through the Agency's website, and facilitate the disclosure of such documents via their publication on the Agency's website or through other electronic means, where appropriate. The format and the scope of this register as well as rules on the publication of documents on the Agency's website and their disclosure to the public through electronic means will be established by the Director.
2. The register shall contain the title of the document (in the languages in which it is available), references, an indication of its author and the date of its creation or adoption.
3. A help page shall inform the public how the document can be obtained. If the document is published, there shall be a link to the full text.

Article 9

Documents directly accessible to the public

The following documents shall be automatically provided on request and, as far as possible, made directly accessible by electronic means:

- a. documents adopted by the Agency for publication in the Official Journal of the European Communities;
- b. documents already disclosed following a previous application;
- c. documents originating from third parties which have already been disclosed by their author or with the consent of the author.

Article 10

Report

In accordance with article 17 of Regulation (EC) No 1049/2001, information concerning the implementation of this decision, in particular statistics on the number of requests for access to Agency documents, the number of refusals, and the reasons for such refusals shall be published in the Agency's annual activity report which shall be adopted and submitted to the Commission by the Steering Committee.

Article 11
Entry into force

This decision shall take effect on the date of its adoption by the Steering Committee. It shall be made available on the homepage of the Agency's website.

Done at Brussels, on.....

For the HaDEA Steering Committee
(*e-signed*)
The Chairperson