



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Brussels,
SANTE/DG (2022)

Ms Lora Verheecke
9 rue du Bronze 1070
Brussels Belgium

By email only with acknowledgement of receipt:
ask+request-10780-87a36cab@asktheeu.org

Subject: Your application for access to documents – GESTDEM 2022/1270

Dear Ms Verheecke,

We refer to your email of 2 March 2022 in which you make a request for access to documents, registered on the same date under the above-mentioned reference number.

1. Scope of your request

On the basis of Regulation (EC) No 1049/2001, you requested access to the following documents:

- *Any documents, including briefings, reports, correspondence (email or other), between DG Sante and any external stakeholders where the European Health Data Space is concerned or mentioned.*
- *A list of meetings, as well as agendas and minutes or any other reports of such meetings, since 1st January 2021, between officials/representatives/experts of DG Sante and any external stakeholders related directly or indirectly to the European Health Data Space..*

We also refer to our email of 23 March 2022 extending the time limit to respond to your request according to Article 7(3) of Regulation (EC) No 1049/2001.

Moreover, we refer to your e-mail of 30 March 2022 in reply to our fair solution request of 28 March 2022.

2. Identification and assessment of relevant documents

We have identified 63 documents that fall within the scope of your request.

You will find attached a table listing the identified documents and summarising the outcome of the assessment carried out on the basis of Regulation (EC) No 1049/2001.

Having examined the documents requested under the provisions of Regulation (EC) No 1049/2001 regarding public access to documents, I have come to the conclusion that:

- Full access can be granted to the following document: Documents 2.b, 3.c, 7.d, 7.e, 9.b, 12.c, 15.a, 15.f, 16.a, 17.a, 17.b, 17.e, 17.f, 17.g, 17.h and 17.i.
- Partial access can be granted to the following document as their full disclosure is prevented by one or several exceptions to the right of access laid down in Article 4 of the Regulation: Document 1, 2.a, 3.a, 3.b, 4, 5, 6, 7.a, 8.a, 8.b, 8.c, 9.a, 10.a, 10.b, 11.a, 11.b, 12.a, 12.b, 12.d, 13.a, 13.b, 14, 15.b, 15.c, 15.d, 15.e, 15.g, 15.h, 15.i, 15.j, 15.k, 16.b, 17.c, 17.d, 18.a, 18.b, 18.c, 19, 20.a, 20.b, 21.a, 21.b, 21.c, 22.a, 22.b.
- Refusal to Access is linked with the documents 7b and 7c based on the exceptions of Article 4 of the Regulation

We enclose a copy of the documents redacted of the parts which cannot be disclosed as further explained below.

You may reuse public documents, which have been produced by the European Commission or by public and private entities on its behalf based on the [Commission Decision on the reuse of Commission documents](#). You may reuse the documents disclosed free of charge and for non-commercial and commercial purposes provided that the source is acknowledged and that you do not distort the original meaning or message of the documents. Please note that the Commission does not assume liability stemming from the reuse.

Please note that documents originating from third parties are disclosed to you based on Regulation (EC) No 1049/2001. However, this disclosure is without prejudice to the rules on intellectual property, which may limit your right to reproduce or exploit the released documents without the agreement of the originator, who may hold an intellectual property right on them. The European Commission does not assume any responsibility from their reuse. They do not reflect the position of the Commission and cannot be quoted as such.

As to the minutes or a summary record of a meeting with external parties, these documents were drawn up for internal use under the responsibility of the relevant services/officials of the Directorate-General for SANTE. They solely reflect the services'/ author's interpretation of the interventions made and do not set out any official position of the third parties to which the document refers, which was not consulted on its content. They do not reflect the position of the Commission and cannot be quoted as such.

3. Partial disclosure of documents

3.1. Protection of the privacy and integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data - Article 4(1)(b) of Regulation (EC) No 1049/2001

With regard to the document 1, 2.a, 3.a, 3.b, 4, 5, 6, 7.a, 8.a, 8.b., 8.c, 9.a, 10.a, 10.b, 11.a, 11.b, 12.a, 12.b, 12.d, 13.a, 13.b, 14, 15.b, 15.c, 15.d, 15.e, 15.g, 15.h, 15.i, 15.j, 15.k, 16.b, 17.c, 17.d, 18.a, 18.b, 18.c, 19, 20.a, 20.b, 21.a, 21.b, 21.c, 22.a, 22.b., a complete disclosure of the identified documents is prevented by the exception concerning the protection of privacy and the integrity of the individual outlined in Article 4(1)(b) of Regulation (EC) No 1049/2001, because they contain the following personal data:

- the names/initials and contact information of Commission staff members not pertaining to the senior management;

- the names/initials and contact details of other natural persons;
- other information relating to an identified or identifiable natural person.
- handwritten signatures/abbreviated signatures of natural persons;

Article 9(1)(b) of the Regulation (EU) 2018/1725 (“EUDPR”) «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...» does not allow the transmission of these personal data, except if you prove that it is necessary to have the data transmitted to you for a specific purpose in the public interest and where there is no reason to assume that the legitimate interests of the data subject might be prejudiced. In your request, you do not express any particular interest to have access to these personal data nor do you put forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest.

Consequently, I conclude that, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data contained in the requested documents, as the need to obtain access thereto for a purpose in the public interest has not been substantiated and there is no reason to think that the legitimate interests of the individuals concerned would not be prejudiced by disclosure of the personal data concerned.

In accordance with the above mentioned, partial access is granted to the mentioned documents, expunged of personal data.

3.2. Protection of public interest, as regards international relations – Article 4(1)(a), third indent, of Regulation (EC) No 1049/2001 and Protection of the commercial interests of a legal person - Article 4(2), first indent, of Regulation (EC) No 1049/2001

As explained below in section 4., access to documents No. 7.b and 7.c is refused, following a consultation of a third party from whom the documents originate. Document No. 7.a has been drawn up by the Commission but relates to exchanges between the Commission and a third party concerning the same events as documents No. 7.b and 7.c. Consequently, full disclosure of the document No. 7.a would put at risk the protection of the interests for which the access to documents No. 7.b and 7.c is refused (see below section 4.). Related parts of the document 7.a are therefore redacted.

4. Refusal regarding the disclosure of the documents

4.1. Protection of public interest, as regards international relations – Article 4(1)(a), third indent, of Regulation (EC) No 1049/2001

Document No 7.b constitutes exchanges between the Commission and a third party and it contains information whose disclosure would undermine the international relations. Since the identified document originates from a third party, the originator of the documents has been consulted, in accordance with Article 4(4) of Regulation (EC) No 1049/2001, to assess whether an exception under Article 4 of this Regulation is applicable. The originator of the document has objected to the full disclosure of document 7b as its disclosure would undermine the protection of public interest, as regards international relations. Specifically, the disclosure of the document at hand could give rise to speculation about a third party’s interest in European Health Data Space proposal, measures and/or involvement (or lack thereof) in the legislative process.

4.2. Protection of the commercial interests of a legal person - Article 4(2), first indent, of Regulation (EC) No 1049/2001

The originator of Documents No 7.b and 7.c also indicated that the two documents contain information whose disclosure would undermine the commercial interest of a legal person, as they include industrial information and information covered by intellectual property. Namely, these documents contain information whose disclosure would undermine the commercial interests of legal persons as it would reveal the names of companies whose representatives potentially participated in the respective discussions. This would give rise to speculation about the nature of such companies' interest in the European Health Data Space and/or whether they were involved in the legislative process.

4.3. Article 4(6) of the Regulation (EC) No 1049/2001

We have considered whether partial access could be granted to these documents according to Article 4(6) of the Regulation (EC) No 1049/2001. However, we have come to the conclusion that the documents are entirely covered by the above exception to the right of access to documents.

Therefore, no access can be granted to documents 7.b and 7.c.

5. Overriding public interests

The exceptions to the right of access provided for in Article 4(2) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing the requested document. In your application, you did not submit any grounds concerning a public interest on the basis of which the interests protected in Regulation (EC) No 1049/2001 would have to be overridden, and we could not identify any such ground either. In these circumstances, we have to conclude that there is no evidence of an overriding public interest in disclosure, in the sense of Regulation (EC) No 1049/2001.

6. Means of redress

In accordance with Article 7(2) of Regulation (EC) No 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretary-General of the Commission at the following address:

European Commission
Secretariat-General
Transparency, Document Management & Access to Documents (SG.C.1)
BERL 7/076
B-1049 Bruxelles

or by email to: sg-acc-doc@ec.europa.eu

7. Acknowledgment of receipt

According to the standard operational procedure, the reply is sent by e-mail only. We would therefore appreciate if you could explicitly confirm receipt of the e-mail within 5 working days by replying to SANTE-CONSULT-C1@ec.europa.eu

Yours sincerely,

-e-signed-

Sandra GALLINA
Director General

Enclosures: Table of documents (as mentioned in section 2) and disclosed documents.