



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Digital Health, European Reference Networks

Brussels,

SANTE/B3

By e-mail only:
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Subject: Your application for access to documents – GESTDEM 2022/2113

Dear Mr Sangiao,

We refer to your e-mail dated 7 April 2022 in which you make a request for access to documents, registered on 11 April under the above-mentioned reference number.

We also refer to our email of 5 May 2022 extending the time limit to respond to your request according to Article 7(3) of Regulation (EC) No 1049/2001¹.

We also refer to our email of 30 June 2022 informing you of the delay in replying to your request due to the ongoing third-party consultation of the documents covered in the scope of this request.

1. Scope of your request

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

“La respuesta a estos cuestionarios que pide la DG Sante a los Estados miembros:

https://urldefense.com/v3/__https://www.asktheeu.org/en/request/9913/response/35888/attach/15/doc*2022*201*20EU*20DCC*20statistics*20ES*20ANNEX*20OF*20ES*20STATS.pdf?cookie_passthrough=1__;JSULJSULJSULJQ!!DOxrgLBm!WX892VzRfB4ZsMBB

¹ Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

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GrsAAQ\$

Solicito que se me facilite el último cuestionario de este tipo rellenado por cada uno de los Estados miembros. Solicito, además, los documentos donde se explica a los Estados miembros qué deben rellenar en cada apartado y que se me informe de que se contabiliza como "number of cross-border verifications" y "number of errors".

2. Identification and assessment of relevant documents

We have identified 9 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.

Since the documents originate from third parties in accordance with Art. 4(4) of Regulation, the originators of the documents have been consulted in order to assess whether an exception established in Article 4 applies to these documents

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

- Full access can be granted to documents 1.b and 3.b.
- Partial access can be granted to documents 1.a, 2., 3.a, 4., 5., 6.a and 6.b as their full disclosure is prevented by one or several exceptions to the right of access laid down in Article 4 of the Regulation: Documents

We enclose a copy of the documents 1.b and 3.b and 1.a, 2., 3.a, 4., 5. 6.a and 6.b, redacted of the parts which cannot be disclosed as further explained below.

Please note that documents originating from third party 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.

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 documents 1.a, 2., 3.a, 4., 5. 6.a and 6.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.

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.

4. 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 Brussels

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

Yours sincerely,

Martin DORAZIL
Deputy Head of Unit

Enclosure: Attached table of documents (as mentioned in section 2) and disclosed documents.