



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels,
SANTE/E2/(2022)7628253

***By registered mail with
acknowledgment of receipt***

Mr. Sean Finan,
Derryheen, Butlersbridge Cavan,
Republic of Ireland
H12 RP27

By email only:
[ask+request-11683-
f72e444e@asktheeu.org](mailto:ask+request-11683-f72e444e@asktheeu.org)

Dear Mr. Finan,

Subject: Your application for access to documents – Ref GestDem No 2022/4517

We refer to your request for access to documents, registered on 8 August 2022 under the above-mentioned reference number.

We also refer to our email dated 6 September 2022 in which we have informed you that an extended time limit is needed as the documents requested originate from third parties which have been consulted.

1. Scope of your request

In your request, you ask on the basis of Regulation (EC) No 1049/2001¹ access to:

‘All documents, whenever created, related to the changes to the EU Novel Food Catalogue entries for cannabidiol and cannabinoids in or around January 2019, including but not limited to meeting agendas, meeting minutes, letters, email communications or other correspondence, submissions, reports, etc.

In particular (but not limited to),

- *minutes of meetings of the Working Group on Novel Foods related to cannabidiol and cannabinoid from 2018 and 2019; and*
- *records of Member State discussions, draft proposals, comments on proposals, and Member State submissions on proposals relevant to meetings of the Working Group on Novel Foods in 2018 and 2019.’*

2. Identification and assessment of the relevant documents

We have identified 29 documents that fall within the scope of your request.

The Annex of this letter contains a list of the identified documents and summarises the outcome of the assessment carried out on the basis of Regulation (EC) No 1049/2001² regarding public access to documents.

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

Since the above mentioned documents originate from third parties, the originators of the documents have 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 to the identified documents.

Having examined these documents under the provisions of Regulation (EC) No 1049/2001 and considered the opinion of the third parties, we came to the conclusion that:

- Full access can be granted to documents listed under points 1 and 17;
- partial access can be given to documents listed under points from 2 to 16, and from 18 to 29 of the Annex. These documents may be only partially disclosed as their full disclosure is prevented by the exceptions to the right of access laid down in Article 4 of Regulation (EC) No 1049/2001.

Please find enclosed the documents listed under points from 2 to 16, and from 18 to 29 of the Annex, redacted of the parts which cannot be disclosed as they are covered by the exceptions to the right of access laid down in Article 4 of Regulation (EC) No 1049/2001. Please note that parts out of the scope of your request have been withheld and labelled as “out of scope”.

As regards the documents listed under points from 2 to 4, 7 to 9, 12 to 15, 17, 19 to 20, 22, 24 to 26 and 29, 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.

With regard to the documents listed under points 5, 6, 10, 11, 16, 18, 21, 23, 27 and 28 you may reuse the document requested free of charge, 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 document. Please note that the Commission does not assume liability stemming from the reuse.

3. Reasons for partial refusal

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

The originators of the document listed in point 22 of the Annex has objected to the full disclosure of the document. They have motivated this by invoking the argument that the disclosure of the whole document would undermine their commercial interests, including intellectual property.

On the basis of the assessments made by the third party, we have considered that the exception of Article 4(2), first indent, of Regulation (EC) No 1049/2001, applies partially to the document listed in point 22 of the Annex which is disclosed expunged from those parts containing the confidential information.

As a consequence, and taking into account the opinion of the third party, we regret to inform you that access to the document listed in point 22 of the Annex can be only partially granted, as full disclosure is prevented by one exception to the right of access laid down in Article 4(2) first indent of Regulation (EC) No 1049/2001.

² Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

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 listed under points 2 to 5, 7 to 10, 12 to 15, 17, 19 to 22, 24 to 26, and 29 of the Annex, a complete disclosure 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 and contact details of natural persons;
- handwritten signatures of natural persons.
- other information relating to an identified or identifiable natural person including their job titles.

Article 9(1)(b) of the Data Protection Regulation (EU) 2018/1725³ 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 argument to establish the necessity to have the data transmitted for a specific purpose in the public interest.

Consequently, we 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.

Therefore, we are disclosing the documents listed under points 2 to 5, 7 to 10, 12 to 15, 17, 19 to 22, 24 to 26, and 29 of the Annex related to your request expunged from this personal data.

4. Overriding public interest

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.

5. 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:

³ 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 (OJ L 295, 21.11.2018, p. 39).

European Commission
Secretary-General
Transparency, Document Management & Access to Documents (SG.C.I)
BERL 7/076
B-1049 Brussels

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

6. 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-e2@ec.europa.eu.

Yours sincerely,

Sandra GALLINA

Enclosure:
Annex - List of documents and disclosed documents