Dear Mr Meunier,

Subject: Your application for access to documents – EASE 2024/0497

We refer to your email of 26 January 2024 in which you make a request for access to documents registered on the same day under case number EASE 2024/0497 (1).

We also refer to our letter of 15 February 2024 (2) extending the time limit to respond to your request according to Article 7(3) of Regulation (EC) No 1049/2001 (3).

1. Scope of the request:

In your request, you ask on the basis of Regulation (EC) No 1049/2001, access to:

“Any documents since October 2023 the 17th that do discuss or mention new genetic modification techniques (those latter can also be referred to as genome editing, new plant breeding, new genomic techniques, new biotechnologies etc.) in relation to their regulation and/or regulatory status and/or in relation to their claimed benefits or risks, including correspondence (emails or other), reports, briefings, as well as attachments, and a list of meetings (since 17 October 2023) with detailed minutes and any other reports of such meetings.

This also includes documents exchanged between DGs, as well as between the Commission and EU Member States, third countries and/or permanent representations.

I also request any messages exchanged via whatsapp, SMS, or any other communication channel between the DG SANTE Biotechnology Unit and

(1) Ares(2024)612539
(2) Ares(2024)1150313
Please note that the scope of your request covers also areas falling under the responsibility of the Secretariat General, a separate access to documents request was registered under the reference EASE 2024/0709. Therefore, this reply (with reference EASE 2024/0497) does not include documents originating from the Secretariat General. You will receive their reply in due course.

In our letter of 15 January 2024 (4) we invited you, pursuant to Article 6(3) of Regulation (EC) No 1049/2001, to propose a fair solution for dealing with your request, inviting you to narrow the scope or/and choose up to 30 documents from the list of documents provided along with our letter. The amount of 30 documents corresponds to the maximum number of documents which can be assessed within the deadline set out in Regulation (EC) No 1049/2001.

In your reply of 16 January 2024 (5), you agreed to reduce the scope of your request to 30 documents, which are listed in the Annex A, here attached. Only access to these documents has been assessed under Regulation (EC) No 1049/2001.

Please note that document No 55 from the list proposed for the fair solution featured on the list by mistake; this this document does not fall into the scope of your request and therefore it has been removed from the list in Annex A. In addition, certain documents from the list proposed for the fair solution contain attachments; these attachments have been added to the above-mentioned list. In consequence, the total number of documents considered as falling into the scope of the request in subject, listed in Annex A, amounts to 34.

2. Identification and assessment of the documents

You will find attached a table (Annex A) listing the 34 identified documents and summarising the outcome of the assessment carried out on the basis of Regulation (EC) No 1049/2001.

Since documents No 1, 2, 3, 4, 5, 6, 7, 12, 17, 18, 23 and 24 originate from third parties, the originators of these documents have been consulted in order to assess whether an exception established in Article 4 of the Regulation applies.

Having examined the 34 documents under the provisions of Article 4 of Regulation (EC) No 1049/2001 and considered the opinion of third parties concerned, we have come to the following conclusion:

- Full access can be given to documents No 2, 5, 7, 18, 24, 26, 27, 29, 30, 32, 33 and 34.
- Partial access can be given to documents No 1, 3, 4, 6, 8, 12, 15, 16, 17, 19, 21, 22, 23, 25, 28 and 31, 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 listed below.

(4) Ares(2024)1153602
(5) Ares(2024)1185575
- No access can be given to documents No 11 and 20, as their disclosure is prevented by the exceptions to the right of access laid down in Article 4 of Regulation (EC) No 1049/2001 listed below.

- Documents No 9, 10, 13 and 14 are publicly available and can be accessed through the following hyperlinks:
  - Documents No 9 and 10:  
  - Documents No 13 and 14:  

We enclose a copy of documents No 2, 5, 7, 18, 24, 26, 27, 29, 30, 32, 33 and 34 as well as a copy of documents No 1, 3, 4, 6, 8, 12, 15, 16, 17, 19, 21, 22, 23, 25, 28 and 31, redacted of the parts that 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.

Briefings for and minutes of meetings were drawn up for internal use under the responsibility of the relevant services of the Directorate-General for Health and Food Safety. They solely reflect the service’s interpretation of the interventions made and do not set out any official position of the third parties to which the document refers, which were not consulted on their content. They do not reflect the position of the Commission and cannot be quoted as such.

### 3. Justifications for partial disclosure

#### a) Article 4(1)(b) of Regulation (EC) No 1049/2001 – Protection of privacy and the integrity of the individual

A complete disclosure of documents No 1, 3, 4, 6, 8, 12, 15, 16, 17, 19, 21, 22, 23, 25, and 31 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’s staff members not pertaining to senior management;
- the names(initials and contact details of other natural persons.
Article 9(1)(b) of the Data Protection Regulation (6) 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, 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 above mentioned 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.


A complete disclosure of the documents No 28 and 31, is prevented by the exception concerning the protection of the institution's decision-making process, as laid down in the Article 4(3), first subparagraph of Regulation (EC) No 1049/2001.

Documents No 28 and 31 contain contributions to briefings for senior management in DG SANTE and the responsible Commissioner, respectively, related to the legislative proposal on NGTs currently in the ordinary legislative procedure. The documents were drafted by the Commission services for internal use. Information provided in the redacted parts, if disclosed, would provide third parties with an effective mean to exert pressure on the negotiating institutions and affect the possible intervention of the Commission in those negotiations. Given the public attention raised by the proposal currently debated by legislators, this risk is not purely theoretical.

In particular, in document No 28, the redacted parts contain the Commission services’ views and elements for an internal discussion in relation with the negotiation of the legislative proposal in question. Disclosure, at this stage of the procedure, of such internal views would bring a serious risk to compromise the Commission’s position in the negotiations of the legislative proposal at stake.

It results from the above that the exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 applies to those parts of document No 28.

In particular, in document No 31, the redacted parts contain the Commission services’ evaluation of the positions of Member States regarding specific points of the legislative proposal at stake. The release of the current positions of individual Member States to the public at this stage of the discussions would seriously undermine the Council’s position in the negotiations of the proposal, therefore, the access to this information must be refused.

It results from the above that the exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 applies to those parts of document No 31.

In accordance with the above mentioned, partial access is granted to documents No 28 and 31, expunged of information that would undermine the protection of the institution's ongoing decision-making process.

4. Justification for refusal of documents

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

Following an examination of documents No 11 and 20 under the provisions of Regulation (EC) No 1049/2001 regarding public access to documents, I regret to inform you that your application cannot be granted, as disclosure is prevented by exception to the right of access laid down in the first indent of Article 4(2) of this Regulation.

These documents contain an e-mail from the third party, with in attachment a position paper which is fully released (document No 12) as well as a further exchange.

These documents originate from a third party, who has been consulted about the release of the documents at stake pursuant to Article 4(4) of Regulation (EC) No 1049/2001. The third party has objected to the disclosure of these documents based on the exception in Article 4(2), first indent, of Regulation (EC) No 1049/2001, protection of the commercial interests, including intellectual property.

The third party considers that these documents contain commercially sensitive information whose disclosure would undermine the protection of commercial interests of the organisation and that therefore a refusal to disclose this document is covered by Regulation (EC) No 1049/2001 Article 4(2), first indent.

In accordance with the above mentioned, no access can be granted to these documents.

We have considered whether partial access could be granted to these documents, in accordance with Article 4(6) of the Regulation. However, it follows from the assessment made above that the documents No 11 and 20 are entirely covered by the exceptions or the remaining parts after expunging the confidential information might be meaningless or illegible.

5. Overriding public interest

The exception to the right of access provided for in the first indent of Article 4(2) and 4(3) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing the redacted part of the requested documents.

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 to the Secretariat-General of the Commission within 15 working days upon receipt of this letter. You can submit it in one of the following ways:

**by mail:**
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

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-e3@ec.europa.eu.

Yours sincerely,

Sandra GALLINA
Director General

Enclosures: List of documents Annex A and disclosed documents