



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels  
SANTÉ E.3

Mr Eric Meunier  
Rue Saint Sabin, 38  
B-75011 Paris  
France  
*By e-mail with acknowledgement of receipt: Ask+request-13708-a4bc7359@asktheeu.org*

Dear Mr Meunier,

**Subject: Your application for access to documents – EASE 2023/6117**

We refer to your email of 17 October 2023 in which you make a request for access to documents registered on the same day under case number EASE 2023/6117 <sup>(1)</sup>.

We also refer to our letter of 9 November 2023 <sup>(2)</sup> extending the deadline for handling of your request according to Article 7(3) of Regulation (EC) No 1049/2001<sup>(3)</sup>.

**Scope of the request:**

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

*“Any documents since may 2023 the 25th 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 25 may 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 SANTÉ Biotechnology Unit and*

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<sup>(1)</sup> Ares(2023)7044239

<sup>(2)</sup> Ares(2023)7605877

<sup>(3)</sup> Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

*representatives of Croplife EU, Bayer, BASF, Syngenta, Corteva or any companies; and/or any member of the Agriculture committee of the European Parliament; and/or any member of the Environment committee of the European Parliament, for the same period.”*

In our letter of 16 November 2023 <sup>(4)</sup>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 DG SANTE 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 20 November 2023 <sup>(5)</sup>, 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.

After the receipt of your reply to the fair solution letter, we found six additional documents falling into the scope of your request; these documents have been added to the final reply.

In consequence, the total number of documents considered as falling into the scope of the request in subject amount to 36.

### **1. Identification and assessment of the documents**

You will find attached a table (Annex A) listing the 36 identified documents and summarising the outcome of the assessment carried out on the basis of Regulation (EC) No 1049/2001.

Since documents No 11 and 31 originate from a third party, the originator of these documents has been consulted in order to assess whether an exception established in Article 4 of the Regulation applies.

Having examined the 36 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 1, 2, 5, 6 and 12;
- Partial access can be given to documents No 3, 4, 9, 10, 11, 13, 14, 15, 16, 17, 31, 32, 33, 34, 35 and 36, 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;
- No access can be given to documents No 7, 8, 8.1 and to documents No 18 to 30, 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.

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<sup>(4)</sup> Ares(2023)7796799

<sup>(5)</sup> Ares(2023)7925477

We enclose a copy of documents No 1, 2, 5, 6 and 12 fully disclosed as well as a copy of documents No 3, 4, 9, 10, 11, 13, 14, 15, 16, 17, 31, 32, 33, 34, 35 and 36, 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.

Meeting briefings and minutes were drawn up for internal use under the responsibility of the relevant services of the Directorate-General for Health and Food Safety. It solely reflects the service's interpretation of the interventions made and does not set out any official position of the third parties to which the document refers, which was not consulted on its content. It does not reflect the position of the Commission and cannot be quoted as such.

## **2. Justifications for partial disclosure**

### 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 3, 4, 9, 10, 11, 13, 14, 15, 16, 17, 31, 32, 33, 34, 35 and 36 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;
- handwritten signatures/abbreviated signatures of natural persons;
- other information relating to an identified or identifiable natural, such as other handwritten text, profile photos.

Article 9(1)(b) of the Data Protection Regulation <sup>(6)</sup> 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.

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<sup>(6)</sup> 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).

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 document, 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, partial access is granted to documents No 3, 4, 9, 10, 11, 13, 14, 15, 16, 17, 31, 32, 33, 34, 35 and 36 expunged of personal data.

### **3. Justification for refusal of documents**

*Protection of the institution's decision-making process - Article 4(3), second subparagraph of Regulation (EC) No 1049/2001*

Having examined documents No 7, 8, 8.1 and from 18 to 30, we regret to inform you that access cannot be granted, as their disclosure is prevented by the exception concerning the protection of the institution's decision-making process, as laid down in the Article 4(3), second subparagraph of Regulation (EC) No 1049/2001.

**Documents No 8 and 8.1** contain exchanges with the external contractor supporting the impact assessment for a proposal for a new Regulation on plants obtained by certain new genomic techniques. The Commission's legislative proposal, accompanied by its impact assessment, was adopted on 5 July 2023 <sup>(7)</sup>. On the same date, the Commission published the final report of the external contractor <sup>(8)</sup>.

The published external report contains all the information and materials prepared by the contractor to support the impact assessment, in their final version. Conversely, the documents requested are drafts of the final report, as well as exchanges with the Commission with a view to their finalisation, at a time when the work (of collecting or analysing evidence, or of quality review) was on-going. Such documents are not always based on all the evidence considered and reflect partial or incomplete assessments of the evidence.

Disclosing such documents, which do not represent the final output of the external contractor, would risk creating confusion and misunderstandings about the materials and evidence that support the Commission's impact assessment. This could seriously undermine the Commission's decision-making process during the ongoing interinstitutional negotiations on the legal proposal, of which an important element is the impact assessment that underpins it. As the area of new genomic techniques is a particularly sensitive policy area, it is especially important to base the discussions on the proposal, on the robust underlying evidence as presented and analysed by the impact assessment and the finalised contractor report.

It results from the above that the exception laid down in Article 4(3) second subparagraph of Regulation (EC) No 1049/2001 applies to the above-mentioned documents.

We have considered whether partial access could be granted to documents No 8 and 8.1, in accordance with Art. 4 (6) of Regulation. However, it follows from the assessment

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<sup>(7)</sup> The proposal, the impact assessment and other supporting documents are available at [https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology\\_en](https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en)

<sup>(8)</sup> <https://op.europa.eu/en/publication-detail/-/publication/44b784a1-1ae3-11ee-806b-01aa75ed71a1/language-en>

made above that these documents are entirely covered by the exceptions and the remaining parts after expunging the confidential information is meaningless.

**Document No 7** is an internal note containing information about open issues in the preparation of the legislative proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, while **documents No 18 – 30** contain the inter-service consultation of the draft proposal in question as well as the replies of the consulted Commission services.

The above-mentioned documents contain opinions for internal use and are part of deliberations and consultations within the Commission. Even if the internal decision-making process within the Commission related to the adoption of the legislative proposal in question has been finalised, disclosure of the documents, before the conclusion of the inter-institutional legislative process, would negatively affect the possibility of expressing views independently within an institution. Ensuring the protection of such internal consultations allows internal discussion with a view to improving the functioning of the institution and contributing to the smooth running of the decision-making process. In addition, releasing the documents would risk undermining the position of the Commission in the legislative procedure.

Therefore, the exception laid down in Article 4(3), second subparagraph, of Regulation (EC) No 1049/2001 applies to the above-mentioned documents.

We have considered whether partial access could be granted to the requested documents No 7 and 18 to 30, in accordance with Art. 4 (6) of Regulation. However, it follows from the assessment made above that these documents are entirely covered by the exceptions and the remaining parts after expunging the confidential information is meaningless.

#### **4. Overriding public interest**

The exception to the right of access provided for in the second subparagraph of Article 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.

#### **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 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](mailto: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-e3@ec.europa.eu](mailto:sante-consult-e3@ec.europa.eu).

Yours sincerely,

Sandra GALLINA  
Director General

Enclosures:           List of documents Annex A and disclosed documents