



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels,  
SANTE E3/AT/gk(2021)654499

***By registered letter with  
acknowledgment of receipt***

Ms Nina Holland  
Corporate Europe Observatory (CEO)  
Rue d'Edimbourg, 26  
B - 1050 Brussels

***Advance copy by e-mail to  
[nina.holland@corporateeurope.org](mailto:nina.holland@corporateeurope.org)***

Dear Ms Holland,

**Subject: Your application for access to documents – GestDem 2020/6973**

We refer to your email dated 13 November 2020 in which you make a request for access to documents under Regulation (EC) No 1049/2001 regarding public access to documents<sup>1</sup>, registered on the same date under the above-mentioned reference number.

On 25 November 2020 we send you a request for clarification of the scope, to which you replied on 15 December 2021.

We also refer to our email dated 14 January 2021, in which we, in accordance with Article 7(3) of Regulation (EC) No 1049/2001, extended the time-limit to respond to your request.

### **1. Scope of the request**

You have requested access, on the basis of Regulation (EC) No 1049/2001, to:

*“Any documents since 07 April 2020, including briefings, reports, correspondence (email or other), as well as attachments, and a list of meetings (also since 07 April 2020) with detailed minutes and any other reports of such meetings, that contain elements concerning new genetic modification techniques including related patent issues.”*

The scope of the request has further been clarified as *“referring to documents concerning the ongoing work on new genomic techniques led by the Commission”*.

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

We consider your request to cover documents held up to the date of your application, i.e. 13 November 2020.

## 2. Identification and assessment of the documents

We have identified **79** documents (including annexes to main documents) falling under the scope of your request.

Having examined these documents under the provisions of Article 4 of Regulation (EC) No 1049/2001 we have come to the following conclusion:

- The documents No 6, 22, 36 and 60 are publicly available on Europa website and can be accessed through the following link:
  - Document No 6  
[https://ec.europa.eu/food/sites/food/files/plant/docs/reg-com\\_2001-18-ec\\_20201112\\_sum.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/reg-com_2001-18-ec_20201112_sum.pdf)
  - Document No 22  
[https://ec.europa.eu/food/sites/food/files/plant/docs/sc\\_modif-genet\\_20201007\\_sum.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/sc_modif-genet_20201007_sum.pdf)
  - Document No 36  
[https://ec.europa.eu/food/sites/food/files/plant/docs/gmo\\_modern-biotech\\_wg\\_20200918\\_sum.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_modern-biotech_wg_20200918_sum.pdf)
  - Document No 60  
[https://ec.europa.eu/food/sites/food/files/plant/docs/reg-com\\_2001-18-ec\\_20201112\\_agenda.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/reg-com_2001-18-ec_20201112_agenda.pdf)
- The following documents can be fully disclosed: documents No 1a, 5a, 13, 20, 23a, 37, 46a and 61c in Annex A.
- The following documents can be partially disclosed: documents No 1, 3, 4, 4a, 5, 7, 8, 9, 11, 12, 14, 15, 16, 17, 17a, 18, 19, 19a, 21, 23, 24, 25, 26, 26a, 27, 28, 29, 30, 31, 32, 33, 33a, 34, 35, 38, 39, 40, 40a, 41, 42, 43, 44, 44a, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 61 a, and 61b in Annex A.
- Access to **7** documents must be refused (documents No 2, 10, 10a, 10b, 10c, 10d and 45 in Annex A).

You will find attached a table (Annex A) listing the identified documents and summarising the outcome of the assessment carried out on the basis of Regulation (EC) No 1049/2001. You will also find enclosed the documents which are indicated with “Yes” or “Partial” in the table.

Please note that documents No 3, 11, 17, 21, 23, 24, 25, 26, 26a, 28, 29, 35, 43, 47, 51, 53 include parts, which fall outside the scope of your request and are disclosed to you redacted of those parts.

We would also like to draw your attention to the following:

Due to the wide scope of your request, DG SANTE has received some of the documents from other Directorates-General. Each Directorate-General is responsible for the identification and assessment of documents originating from their own services.

Documents No 1, 1a, 4, 4a, 5, 5a, 7, 9, 11, 13, 15, 16, 19, 19a, 20, 23, 23a, 30, 31, 33, 33a, 34, 35, 38, 40, 40a, 44, 44a, 46, 46a, 48, 56, 58, 61, 61a, 61b, 61c in Annex A originate from third parties. 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 without the agreement of the originator, who may hold an intellectual property right on. The European Commission does not assume any responsibility from their reuse.

Documents No 3, 14, 17, 17a, 21, 24, 28, 29, 43, 51, 53 and 59 in Annex A are short reports of meetings between the Commission and third parties drafted for internal purposes. These documents were drawn up for internal use under the responsibility of the relevant Directorate-General. They solely reflect the interpretation of the interventions made and do not set out any official position of the third parties to which the documents refer, which were not consulted on its content. They do not reflect the position of the Commission and cannot be quoted as such.

You may reuse public documents which have been produced by the European Commission or by public and private entities on its behalf - thus excluding those originating from third parties and the reports of meetings - based on the [Commission Decision on the reuse of Commission documents](#). You may re-use the Commission documents disclosed 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 documents. Please note that the Commission does not assume liability stemming from the re-use.

### **3. Reasons for partial refusal**

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

The documents No 1, 3, 4, 4a, 5, 7, 8, 9, 11, 12, 14, 15, 16, 17, 17a, 18, 19, 19a, 21, 23, 24, 25, 26a, 27, 28, 29, 30, 31, 32, 33, 33a, 34, 35, 38, 39, 40, 40a, 41, 42, 43, 44, 44a, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 61 a, 61b, are documents which 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 person

A complete disclosure of the documents that contain personal data 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.

Article 9(1)(b) of the Data Protection Regulation 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 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 document No 1, 3, 4, 4a, 5, 7, 8, 9, 11, 12, 14, 15, 16, 17, 17a, 18, 19, 19a, 21, 23, 24, 25, 26a, 27, 28, 29, 30, 31, 32, 33, 33a, 34, 35, 38, 39, 40, 40a, 41, 42, 43, 44, 44a, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 61 a, 61b, expunged of personal data.

#### **4. Reason for refusal**

Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 (protection of the decision-making process)

Documents No 2, 10, 10a, 10b, 10c, 10d and 45 are refused, as disclosure is prevented by the exception laid down in Article 4(3), third indent, of Regulation (EC) No 1049/2001, which concerns the protection of the decision-making process.

These documents contain studies and other information provided to DG SANTE in the context of reflection on the legal status of new breeding technics.

These documents have been provided to DG SANTE in the context of the ongoing reflection on new breeding technics on which the Commission is still elaborating its position. Disclosure of such documents at the very preliminary stage would seriously undermine the decision-making process of the Commission, as it would reveal preliminary analysis, which are currently under consideration within the institution.

The protection of the decision-making process from targeted external pressure may constitute a legitimate ground for restricting access to documents relating to that process.

The Commission services must remain free to explore all possible options, in the general interest and free from any external pressure, which attempts to compel the Commission to adopt, amend or abandon a policy.<sup>2</sup>

We have assessed whether partial access could be granted to the documents, but we consider that they are entirely covered by the exception.

Having examined the documents No 2 and 45 in the light of the comments from the third party, we consider that the exception of Article 4(3) of Regulation (EC) No 1049/2001 applies to the entire documents. Therefore, access to the documents must be refused.

#### **5. Overriding public interest**

The exceptions to the right of access provided for in Articles 4(2) and 4(3) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing 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

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<sup>2</sup> Judgment of the General Court of 13 November 2015, *ClientEarth v Commission*, joined cases T-424/14 and T-425/14, ECLI:EU:T:2015:848.

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 its 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  
Unit C.1. 'Transparency, Document Management and Access to Documents'  
BERL 7/076  
B-1049 Bruxelles  
or by e-mail to: [sg-acc-doc@ec.europa.eu](mailto:sg-acc-doc@ec.europa.eu)

Yours sincerely,

[e-signed]  
Sandra GALLINA

Enclosures: – Annex A: Table listing the documents covered by the request with assessment  
– 68 documents fully or partially disclosed