



EUROPEAN COMMISSION

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Corporate Europe Observatory
Rue d'Edimbourg 26
1050 Brussels,
Belgium

**DECISION OF THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 4 OF THE
IMPLEMENTING RULES TO REGULATION (EC) No 1049/2001¹**

**Subject: Your confirmatory application for access to documents under
Regulation (EC) No 1049/2001 - GESTDEM 2019/624**

Dear ██████████,

I refer to your email of 8 April 2019, registered on 9 April 2019, in which you submit a confirmatory application in accordance with Article 7(2) of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents² (hereafter: 'Regulation (EC) No 1049/2001').

Please accept our apologies for this late reply.

1. SCOPE OF YOUR REQUEST

In your initial application of 1 February 2019, addressed to Directorate-General for Health and Food Safety, you requested access to:

- '[...] [a]ny documents since 13 July 2018, including briefings, reports, correspondence (email or other), as well as attachments, and a list of meetings (also since 24 April 2017) with detailed minutes and any other reports of such meetings, concerning new plant breeding methods (also called New GM techniques)'.

¹ Official Journal L 345 of 29.12.2001, p. 94.

² Official Journal L 145 of 31.5.2001, p. 43.

Your further specified that, I quote, '[b]y new plant breeding methods, I mean all new techniques currently under debate, including those that were subject of the New Techniques Working Group report (2012) and the subject of various reports by the JRC, and including all genome editing techniques'.

In its initial reply of 18 April 2019, the Directorate-General for Health and Food Safety identified 168 documents falling under the scope of your request.

The Directorate-General for Health and Food Safety granted full access to 53 documents, wide partial access subject to the redaction of personal data under Article 4(1)(b) of Regulation (EC) No 1049/2001 to 109 documents and refused access to 6 documents based on Article 4(3) first subparagraph protecting the decision-making and Article 4(1)(a) third indent protecting the public interest as regards international relations of Regulation (EC) No 1049/2001.

In your confirmatory application, you request a review of this position. In particular, you raise the following concerns:

- Firstly, you argue that documents 81, 94, 100 and 120 cannot be opened as the pdf's are damaged;
- Secondly, you point out that the USB-stick provided only contains documents up to number 148, whereas the list indicates that there are 167 documents;
- Thirdly, you request whether there are back to the office reports related to documents 151, 153, 154, 157, 158, 159, 161, 163, 164 and 166;
- Finally, you contest the refusal to grant access based on Article 4(3) first subparagraph (protection of the decision-making process) to documents 8, 9 and 26.

I would like to clarify the scope of your confirmatory application before undertaking the analysis of the different aspects raised therein.

Firstly, I would like to point out that points 1 and 2 of your confirmatory application relate to administrative errors related to the sending of the documents at initial stage. Please note that these concerns have been addressed by the Directorate-General for Health and Food Safety, which has now sent you the documents in question.³

Secondly, regarding the back-to-the-office reports addressed in point 3 of your confirmatory application, please note that a new initial request was registered by the Directorate-General for Health and Food Safety regarding this point, under reference number GESTDEM 2019/2578. Hence, you received a separate reply regarding this point on 17 June 2019.

³ Initial reply GESTDEM 2019/624 of 30 April 2019, reference Ares(2019)2902482.

Lastly, I note that you do not contest the refusal to grant access based on the exception protecting the public interest as regards international relations provided for in Article 4(1)(a) of Regulation (EC) No 1049/2001 to documents 6, 7 and 84. Consequently, the scope of this decision does not include a review of documents 6, 7 and 84, but is limited to the refusal of the Directorate-General for Health and Food Safety to grant access to documents 8, 9 and 26 based on Article 4(3), first subparagraph (protection of the decision-making process) of Regulation (EC) No 1049/2001.

2. ASSESSMENT AND CONCLUSIONS UNDER REGULATION (EC) No 1049/2001

When assessing a confirmatory application for access to documents submitted pursuant to Regulation (EC) No 1049/2001, the Secretariat-General conducts a fresh review of the reply given by the Directorate-General concerned at the initial stage.

Following the review conducted by the Secretariat-General, I can inform you that partial access is now granted to documents 8, 9 and 26.

Regarding the withheld parts of these documents, the refusal of the Directorate-General for Health and Food Safety to grant access has to be confirmed, for the reasons set out below.

2.1 Protection of privacy and the integrity of the individual

Article 4(1)(b) of Regulation (EC) No 1049/2001 provides that '[t]he institutions shall refuse access to a document where disclosure would undermine the protection of [...] privacy and integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data'.

In its judgment in Case C-28/08 P (*Bavarian Lager*),⁴ the Court of Justice ruled that when a request is made for access to documents containing personal data, Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data⁵ (hereafter 'Regulation (EC) No 45/2001') becomes fully applicable.

Please note that, as from 11 December 2018, Regulation (EC) No 45/2001 has been repealed by 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.⁶

However, the case law issued with regard to Regulation (EC) No 45/2001 remains relevant for the interpretation of Regulation (EU) No 2018/1725.

⁴ Judgment of the Court of Justice of 29 June 2010, *European Commission v The Bavarian Lager Co. Ltd*, C-28/08 P, EU:C:2010:378, paragraph 59.

⁵ Official Journal L 8 of 12.1.2001, p. 1.

⁶ Official Journal L 205 of 21.11.2018, p. 39.

Article 3(1) of Regulation (EU) No 2018/1725 provides that personal data ‘means any information relating to an identified or identifiable natural person [...]’.

Please note that the withheld parts of documents 8 and 26, contain the names, surnames and contact details of staff members of the European Commission not holding any senior management position. They also contain biometric data, such as handwritten notes and signatures.

The names, surnames, contact details and the biometric data of the persons concerned as well as other data from which their identity can be deduced, undoubtedly constitute personal data in the meaning of Article 3(1) of Regulation (EU) 2018/1725.

Pursuant to Article 9(1)(b) of Regulation (EU) No 2018/1725, ‘personal data shall only be transmitted to recipients established in the Union other than Union institutions and bodies if ‘[t]he recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest and the controller, where there is any reason to assume that the data subject’s legitimate interests might be prejudiced, establishes that it is proportionate to transmit the personal data for that specific purpose after having demonstrably weighed the various competing interests’.

Only if these conditions are fulfilled and the processing constitutes lawful processing in accordance with the requirements of Article 5 of Regulation (EU) No 2018/1725, can the transmission of personal data occur.

Furthermore, in Case C-615/13 P (*ClientEarth*), the Court of Justice ruled that the institution does not have to examine by itself the existence of a need for transferring personal data.⁷ This is also clear from Article 9(1)(b) of Regulation (EU) 2018/1725, which requires that the necessity to have the personal data transmitted must be established by the recipient.

According to Article 9(1)(b) of Regulation (EU) 2018/1725, the European Commission has to examine the further conditions for the lawful processing of personal data only if the first condition is fulfilled, namely if the recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest. It is only in this case that the European Commission has to examine whether there is a reason to assume that the data subject’s legitimate interests might be prejudiced and, in the affirmative, establish the proportionality of the transmission of the personal data for that specific purpose after having demonstrably weighed the various competing interests.

In your application, you do not put forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest. Therefore, the European Commission does not have to examine whether there is a reason to assume that the data subjects’ legitimate interests might be prejudiced.

⁷ Judgment of the Court of Justice of 16 July 2015, *ClientEarth v European Food Safety Agency*, hereafter (*ClientEarth v European Food Safety Agency* C-612/13 P), C-612/13 P, EU:C:2015:489, paragraph 47.

Notwithstanding the above, please note that there are reasons to assume that the legitimate interests of the data subjects concerned would be prejudiced by disclosure of the personal data reflected in the documents, as there is a real and non-hypothetical risk that such public disclosure would harm their privacy and subject them to unsolicited external contacts.

Consequently, I conclude that, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data, 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.

2.2 Protection of the decision-making process

Article 4(3) first subparagraph of Regulation (EC) No 1049/2001 provides that '[a]ccess to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure'.

In your confirmatory application, you argue the following: '[t]he regulatory status of modern biotechnologies is an issue of public concern. The ECJ has recently ruled (C-528/16) that the EU GMO regulations also apply to gene editing techniques. This ruling now has to be implemented, and we are aware that the European Commission is in dialogue with national competent authorities in that regard. However, it has not been made clear to the public what "ongoing decision-making process" is under way in the Commission regarding *"the regulation of products obtained with so-called "new breeding techniques"*", what procedures are being followed nor what stakeholders are being invited to provide input. Documents 8, 9 and 26 could hold important information in that respect, and the Commission has not demonstrated why all of the information contained in the documents should be kept secret'.

The documents to which you request access contain exchanges between the Directorate-General for Health and Food Safety and the Cabinet of Commissioner [REDACTED] on the issue of new breeding techniques, in particular:

- Document 8 contains the Directorate-General's for Health and Food Safety views and proposals for follow-up action on the issues relating to new breeding techniques;
- Document 9 is an annex to document 8, which contains a more detailed analysis of some of the issues presented in document 8;
- Document 26 contains the views of the Cabinet [REDACTED] on the Directorate-General's for Health and Food Safety proposals for follow-up.

The withheld parts of the documents concern the clarification of the regulatory requirements applicable to products obtained with new breeding techniques, following the ruling of the Court of Justice of 25 July 2018 in Case C-528/16⁸ and the possible follow-up action. While the ruling has clarified that the requirements of the EU's GMO legislation are applicable to organisms obtained by targeted mutagenesis, certain issues concerning the implementation and application of the ruling still need to be clarified.

This is a highly sensitive issue on which several Member States, industry organisations and non-governmental organisations have been providing opposing views.

The proposed actions and lines to take examined in the documents have not been agreed or finalised within the European Commission, as they concern the very first reflexions on the matter.

Furthermore, the European Commission has engaged with stakeholders, such as Member States, the European Food Safety Authority (EFSA) and the Advisory Group on the Food Chain and Animal and Plant Health on issues related to the implementation of the ruling.

Disclosure of the redacted parts of the documents at this preliminary stage would seriously undermine the protection of the decision-making process of the European Commission regarding ongoing reflexions on the correct implementation of the ruling and the regulatory requirements applicable to new breeding techniques, as it would reveal preliminary analysis and policy options, which are currently under discussion within the institution. Given the highly controversial nature of the debate around these techniques, it is reasonably foreseeable that, should the documents be disclosed, external pressure from stakeholders would be exerted on the European Commission to adopt, amend or abandon a policy option.

Therefore, given the need to protect the ongoing decision-making process of the European Commission and its margin of manoeuvre for exploring all possible policy options free from external pressure, in combination with the highly sensitive nature of the debate, I consider that there is a real and foreseeable risk that the decision-making process on the regulatory requirements applicable to new breeding techniques would be undermined by the disclosure of the redacted parts of the documents.

2.3 Protection of legal advice

Article 4(2), second indent, of Regulation (EC) No 1049/2001 stipulates that '[t]he institutions shall refuse access to a document where disclosure would undermine the protection of: [...] legal advice [...] unless there is an overriding public interest in disclosure.'

⁸ Judgement of the Court of Justice, of 25 July 2018, *Confédération paysanne and Others*, in Case C-528/16, EU:C:2018:583.

Some of the withheld parts of documents 8, 9 and 26 reflect the opinion of the Legal Service of the European Commission on legal aspects concerning new breeding techniques and the regulatory requirements which apply to them.

As recognised by the Court of Justice, the exception protecting legal advice must be construed as aiming to protect an institution's interest in seeking legal advice and receiving frank, objective and comprehensive advice.⁹

Furthermore, the Court of Justice ruled that access to a specific legal opinion might be refused if the opinion is of particularly sensitive nature, provided that the institution gives a detailed statement of the reasons for such a refusal.¹⁰

In the *Access Info Case*, the Court ruled that the preliminary nature of legal advice, the limited number of its recipients and the short notice by which it was given, increase the risk of undermining the capacity of the institution of receiving frank, objective and comprehensive advice in the meaning of Article 4(2) of Regulation (EC) No 1049/2001.¹¹ Furthermore, the Court ruled in this case that if the legal advice does not relate to any specific legislative proposal but it is of a preliminary nature on a number of aspects of EU law, there is less need for openness.¹²

As already explained above, the redacted parts of the documents refer to a legal opinion concerning the clarification of the requirements applicable to new breeding techniques. This clarification was provided in the course of the natural dialogue existing between the services of the European Commission and the Legal Service and does not constitute the final position of the institution on the matter.

Furthermore, the opinion is undoubtedly of a controversial and sensitive nature, as it relates to issues relating to the EU legislation on GMOs.

Under these circumstances, disclosing the withheld parts to the public at this stage would have adverse consequences both for the Legal Service's capacity to assist impartially the European Commission and its services in this sensitive issue and for the European Commission to seek and receive frank, objective and comprehensive legal advice.

It would, therefore, deprive the European Commission of an element essential for the determination of the final position of the institution on the issue at stake.

Consequently, I conclude that access to some parts of documents 8, 9 and 26 must also be refused based on Article 4(2), second indent, of Regulation (EC) No 1049/2001 (protection of legal advice).

⁹ Judgment of the Court of Justice of 1 July 2008, *Sweden and Turco v Council of the European Union*, C-39/05 P and C-52/05, EU:C:2008:374, paragraph 42.

¹⁰ Ibid, paragraph 69.

¹¹ Judgment of the General Court of 7 February 2018, *In't Access Info Europe v Commission*, T-851/16, EU:T:2018:69, paragraphs 90-91.

¹² Ibid, paragraph 90.

2.4 Protection of the public interest as regards international relations

Article 4(1)(a), third indent, of Regulation (EC) No 1049/2001 provides that ‘the institutions shall refuse access to a document where disclosure would undermine the protection of: [...] the public interest as regards [...] international relations’.

Some of the withheld parts of document 8 reflect preliminary views of the European Commission’s services on the positions EU trade partners concerning the regulation of new breeding techniques in the Union.

It has been recognised that Article 4(1)(a) third indent, can be invoked if it is clear that disclosure would harm the EU's international relations with third countries.¹³

Public disclosure of the withheld parts of this document, which reflects internal opinions within the European Commission, would weaken the negotiating position of the EU towards its trade partners in the context of international negotiations, with a potential negative impact on various ongoing trade negotiations.

Given the importance of these negotiations in the general context of good relations between the EU and the third countries concerned, it is absolutely necessary to maintain an atmosphere of mutual trust between the partners. The public release of the withheld parts of the document would undermine this climate of mutual trust. Furthermore, the third countries have consistently opposed disclosure of any information relating to the subject matter in the past.

Please note that it is not possible to provide more detailed explanations without undermining the interests that the use of the invoked exception aims to protect.

In the light of the above, it is evident that there is a reasonable risk that the public disclosure of the document concerned would harm the public interest protected by Article 4(1)(a), third indent of Regulation (EC) No 1049/2001.

3. OVERRIDING PUBLIC INTEREST IN DISCLOSURE

Please note that Article 4(1)(a) of Regulation (EC) No 1049/2001 does not include the possibility for the exceptions defined therein to be set aside by an overriding public interest.

The exceptions laid down in Articles 4(2) and (3) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosure. Such an interest must, firstly, be public (as opposed to any possible private interests of the applicant) and, secondly, overriding, it must outweigh the harm caused by disclosure.

¹³ Judgment of the Court of First Instance of 7 February 2002, *Kuijter v Council*, T-211/00, EU:T:2002:30 paragraphs 62-65.

You argue that, I quote, '[...] the ECJ ruled in case C-60/15, *Saint Gobain vs Commission*, on the basis of the Aarhus Convention and the related EU regulation, that the Commission was not allowed to refuse access to documents holding environmental information. The Aarhus Convention aims to empower people with the rights to access information, participate in decision-making in environmental matters and to seek justice. Early stage deliberations and policy options on how to regulate products from new GM techniques (also called "new breeding techniques" by industry stakeholders) have a clear relevance for the environment, therefore transparency of the Commission's current activity on this issue is in our view required'.

Contrary to what you argue, the Court of Justice did not rule in Case-60/15 P that access to documents containing environmental information can never be refused by the European Commission. In this case, the Court reaffirmed that the exceptions provided for in Article 4 of Regulation (EC) No 1049/2001 must be interpreted in a restrictive way when documents contain environmental information.¹⁴ The same conclusion holds true as regards the Aarhus Regulation, whose recital 15 provides that '[w]here Regulation (EC) No 1049/2001 provides for exceptions, these should apply subject to any more specific provisions in this Regulation concerning requests for environmental information. The grounds for refusal as regards access to environmental information should be interpreted in a restrictive way, taking into account the public interest served by disclosure and whether the information requested relates to emissions in the environment'.¹⁵

Please note that the European Commission has indeed interpreted restrictively the exceptions of Regulation (EC) No 1049/2001, which is clearly demonstrated by the fact that partial access is now granted to the documents in question.

Furthermore, I note that the General Court ruled in Case T-727/15 that there is no automatic overriding public interest when documents relate to environmental issues.¹⁶ In Case C-562/14 P, the Court ruled that a general reference to the need to protect human health is not enough to constitute overriding public interest¹⁷, nor does the general citizens' right to be informed about the compatibility of national law with EU environmental law or the right to participate in decision-making.¹⁸

¹⁴ Judgment of the Court of Justice of 13 July 2017, *Saint-Gobain Glass c European Commission*, C-60/15 P, EU:C:2017:540, paragraph 66

¹⁵ Recital 15 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies, Official Journal L 264 of 6 September 2006, p. 13.
See in this vein Judgment of the Court of Justice of 23 November 2016, *Commission v Stichting Greenpeace v Commission*, C-673/13 P, EU:C:2016:88, paragraph 53.

¹⁶ Judgment of the General Court of 23 January 2017, *Association Justice & Environment, z.s. c European Commission*, T-727/15, EU:T:2017:18, paragraphs 78-80.

¹⁷ Judgment of the Court of Justice of 11 May 2017, *Sweden and Spirlea v Commission*, C-562/14 P EU:C:2017:356, paragraphs 55-58.

¹⁸ *ClientEarth v Commission*, C-612/13 P, paragraphs 91-92.

Consequently, I note that the considerations you put forward are rather of a general nature and would not outweigh the interests protected under Article 4(2) and (3) of Regulation (EC) No 1049/2001.

4. PARTIAL ACCESS

Please note that partial access is granted to the requested documents.

– **5. MEANS OF REDRESS**

Finally, I draw your attention to the means of redress available against this decision. You may either bring proceedings before the General Court or file a complaint with the European Ombudsman under the conditions specified respectively in 263 and 228 of the Treaty on the Functioning of the European Union.

Yours sincerely,

For the Commission

