



EUROPEAN COMMISSION

Brussels, 28.5.2024
C(2024) 3712 final

Ms Suzy Sumner

**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 – 2023/5211**

Dear Ms Sumner,

I am writing in reference to your confirmatory application registered on 14 November 2023, submitted 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 the delay in replying to your request.

1. SCOPE OF YOUR REQUEST

In your initial application of 7 September 2023, handled by the Directorate-General for Health and Food Safety (‘DG SANTE’ hereafter), you requested access to:

- ‘any impact assessments on the Food Information to Consumers Regulation submitted to the Regulatory Scrutiny Board (RSB)
- all RSB opinions on these impact assessments
- a list and minutes of any upstream meetings held between RSB members and staff in the Commission on this file’.

DG SANTE identified the following documents as falling under the scope of your request:

- Impact Assessment, reference Ares(2022)6095823 (hereafter ‘document 1’)
- Minutes of the upstream meeting RSB – SANTE Revision of the Regulation on Food Information to Consumers (hereafter ‘document 2’).

¹ OJ L 345, 29.12.2001, p. 94.

² OJ L 145, 31.5.2001, p. 43.

In its initial reply of 30 October 2023, DG SANTE refused access to these documents based on the exception of the first subparagraph of Article 4(3) (protection of the decision-making process) of Regulation (EC) No 1049/2001.

As regards the Opinion of the Regulatory Scrutiny Board, DG SANTE informed you that the document is subject to another case 2023/3645 in which you submitted a confirmatory application. A decision on whether access to this Opinion can be granted will be taken in the framework of your confirmatory request 2023/3645. Therefore, DG SANTE considered this document falls out of the scope of the current request.

In your confirmatory application, you request a review of this position as far as it concerns documents 1 and 2. You underpin your request with detailed arguments, which I will address below.

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 review of the reply given by the Directorate-General concerned at the initial stage.

Following this review, I have to confirm the initial decision of DG SANTE to refuse access, based on the exceptions of Article 4(1)(b) (protection of privacy and integrity of the individual) and the first subparagraph of Article 4(3) (protection of the decision-making process) of Regulation (EC) No 1049/2001, 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 the 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*)³, 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 data⁴ (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

³ Judgment of the Court of Justice of 29 June 2010, *European Commission v The Bavarian Lager Co. Ltd* (hereafter referred to as ‘*European Commission v The Bavarian Lager* judgment’) C-28/08 P, EU:C:2010:378, paragraph 59.

⁴ OJ L 8, 12.1.2001, p. 1.

movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC⁵ (hereafter ‘Regulation (EU) 2018/1725’).

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

In the above-mentioned judgment, the Court stated that Article 4(1)(b) of Regulation (EC) No 1049/2001 ‘requires that any undermining of privacy and the integrity of the individual must always be examined and assessed in conformity with the legislation of the Union concerning the protection of personal data, and in particular with [...] [the Data Protection] Regulation’⁶.

Article 3(1) of Regulation (EU) 2018/1725 provides that personal data ‘means any information relating to an identified or identifiable natural person [...]’.

As the Court of Justice confirmed in Case C-465/00 (*Rechnungshof*), ‘there is no reason of principle to justify excluding activities of a professional [...] nature from the notion of private life’⁷.

Document 2 contains personal data such as the names and initials of persons who do not form part of the senior management of the European Commission.

The names⁸ 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) 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) 2018/1725, can the transmission of personal data occur.

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 data⁹. This is

⁵ OJ L 295, 21.11.2018, p. 39.

⁶ *European Commission v The Bavarian Lager* judgment, cited above, paragraph 59.

⁷ Judgment of the Court of Justice of 20 May 2003, *Rechnungshof and Others v Österreichischer Rundfunk*, Joined Cases C-465/00, C-138/01 and C-139/01, EU:C:2003:294, paragraph 73.

⁸ *European Commission v The Bavarian Lager* judgment, cited above, paragraph 68.

⁹ Judgment of the Court of Justice of 16 July 2015, *ClientEarth v European Food Safety Agency*, C-615/13 P, EU:C:2015:489, paragraph 47.

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 confirmatory 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.

Notwithstanding the above, there are reasons to assume that the legitimate interests of the data subjects concerned would be prejudiced by the 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, the Secretariat-General concludes 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 the disclosure of the personal data concerned.

2.2. Protection of the decision-making process

The first subparagraph of Article 4(3) of Regulation (EC) No 1049/2001 provides that 'access 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 that DG SANTE has provided 'absolutely no analysis of the possible harms this could cause, nor did [it] provide any proof that such an undermining risk was foreseeable and not merely hypothetical, and therefore have not justified the application of this exception. Also since the legislation seems to currently be "withdrawn" from the European agenda, it is difficult to understand which decision making process it is undermining'.

The documents falling under the scope of the request concern the impact assessment which accompany the legislative proposal for the revision of Regulation (EU) No 1169/2011 on the provision of food information to consumers¹⁰.

Regulation (EU) No 1169/2011 on the provision of food information to consumers establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling. It provides the basis to assure a high level of consumer protection in relation to food information. On 20 May 2020, the Commission adopted the Farm to Fork Strategy¹¹ for a fair, healthy and environmentally friendly food system as part of the European Green Deal. The Farm to Fork Strategy sets out that clear information making it easier for consumers to choose healthy and sustainable diets will benefit their health and quality of life and reduce health-related costs.

As announced on the Commission website dedicated to the subject matter, the revision of the Regulation on food information to consumers is ongoing¹² and the legislative proposal in question has not yet been adopted.

Therefore, the two documents identified in this case concern the ongoing decision-making process in relation to the adoption of the mentioned legislative proposal.

As a standard practice, the impact assessment is published along with the proposal, when the Commission adopts it. However, at the date of the adoption of the present decision, open issues are still under examination. The requested impact assessment is only a draft version that will still evolve, on the basis of the RSB opinion and of on-going discussions among Commission services. The draft impact assessment, to be submitted for adoption to the College of Commissioners together with that proposal, is yet not finalised.

The draft impact assessment contains information about all policy options, their possible impacts, a comparison of the options, details on a preferred option and the methodology for evaluating impacts. Document 2 contains the minutes of the upstream meeting between the Regulatory Scrutiny Board and DG SANTE relating to the preparation of the draft impact assessment. The opinions and comments expressed during the meeting mirror some information in the Impact Assessment.

Releasing the impact assessment or the minutes of the upstream meeting with the Regulatory Scrutiny Board at this stage would reveal preliminary views and policy options, which are currently under consideration and for which no political decision has been taken. Disclosing the documents requested might no longer reflect the current thinking and assessment, and could lead to unnecessary misunderstandings and thus seriously undermine the later adoption by the Commission of the legislative proposal amending Regulation (EU) No 1169/2011. As the revision of Regulation (EU) No 1169/2011 is meant to contribute to the ambitious objectives set under the Green Deal

¹⁰ OJ L 304, 22.11.2011, p. 18–63.

¹¹ https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en

¹² https://food.ec.europa.eu/safety/labelling-and-nutrition/food-information-consumers-legislation/proposal-revision-regulation-fic_en#inception-impact-assessments

and its Farm to Fork Strategy and Europe's Beating Cancer Plan, it is particularly important to have robust underlying evidence for the assessment that will inform the political decision.

The revision of Regulation (EU) No 1169/2011 to ensure better labelling information and help consumers make healthier and more sustainable food choices and tackle food waste requires thorough analysis for which Commission services need the necessary room for reflection and for internal discussion as they must be free to explore all possible options in preparation of the draft legislative proposal. The introduction of harmonised mandatory front-of-pack nutrition labelling, the setting of nutrient profiling criteria to restrict claims made on foods, the extension of mandatory origin or provenance information for certain products, the revision of the rules on date marking and the introduction of mandatory indications of the list of ingredients and the nutrition declaration for all alcoholic beverages have been the subject of political discussions since a long time.

The revision of Regulation (EU) No 1169/2011 has attracted attention from different stakeholders. The Commission so far consulted all stakeholders, including consumer and health organisations and the general public in the framework of the external study supporting the impact assessment, which aimed to collect evidence and data for the analysis of the economic, social and environmental impacts of the policy options proposed for the different initiatives.

The responsible service submitted the draft Impact Assessment to the Regulatory Scrutiny Board for its opinion on 2 September 2022. While the impact assessment has been submitted to the Board, it is still at a preliminary stage as it has to be revised following the opinion and the therein-comprised recommendations. Commission departments are considering changes to the draft impact assessment. As the Commission has not yet adopted legislative proposal, the decision-making process is not completed and is fully ongoing.

At the present stage of the decision-making process, some fundamental elements of the draft impact assessment and its annexes are still under consideration, especially on cost and benefit estimates, impacts on health, consumer behaviour, competitiveness, and SMEs, as well as the analysis and choice of the preferred package of options.

Internal considerations and discussions with other services will still lead to various substantial amendments of the impact assessment and its annexes, in view of the final determination of the preferred options to be adopted in the legislative proposal.

If released now, the content of the redacted parts of the draft Impact Assessment and the minutes of the upstream meeting between the Regulatory Scrutiny Board and DG SANTE could give rise to unwanted external pressure, by various stakeholders who have an interest in this process thus seriously undermining the decision-making process. Strongly divisive and contradictory opinions have been expressed with regard to Front of Pack nutrition labelling and setting of nutrient profiles, origin labelling and alcohol labelling. The impact of the identified options, as assessed, differs significantly.

Providing access to the requested documents would subject the ongoing internal work on the Regulation (EU) No 1169/2011 revision to further external pressure, undermining the objectivity of the impact assessment accompanying the Commission proposal. Considering the state of completion of the impact assessment and draft legislative proposal in question, the stage of the decision-making process and its specific context, as well as the issues still to be discussed internally, the disclosure of the requested documents would seriously undermine further internal work on the legislative proposal and the Commission's decision-making process.

Therefore, disclosure of the documents at this stage would jeopardise the decision-making process in the meaning of the first subparagraph of Article 4(3) of Regulation (EC) No 1049/2001.

Consequently, the Secretariat-General considers that there is a reasonably foreseeable and not purely hypothetical risk that public disclosure of the documents 1 and 2 would bring a serious harm to the decision-making process concerned.

In light of the above, the Secretariat-General concludes that documents 1 and 2 need to be protected on the basis of the exception laid down in the first subparagraph of Article 4(3) of Regulation (EC) No 1049/2001 and that further access thereto must be refused.

3. OVERRIDING PUBLIC INTEREST IN DISCLOSURE

The exception laid down in Article 4(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 and, secondly, outweigh the harm caused by disclosure.

In your confirmatory application, you consider that there is an overriding public interest in disclosing the documents requested. You claim that 'the burden is on the EU body to identify the public interest' and you indicate several matters that the Commission should take into consideration.

You argue that 'the content of this legislation is of fundamental concern to the health of European citizens. It concerns information that we should all know about the food we consume on a daily basis and provisions which should help us not be misled by the food industry. Non-communicable diseases are putting financial and societal pressure on our countries, and yet legislation on what is in our food and associated health and nutrition claims, as well as a front of pack nutritional label which is accessible to all is being delayed, or even cancelled'.

Second, you argue that 'documents have been shared which show the pressure of the agro-industry and Italy in the weeks before this legislation should have been released. Analysis by BEUC [...] draws conclusions of influence in this legislation. Given that it is known that there has been lobbying, it is important that full information is available to the public so as to ensure that the public interest is being taken into account in the proposals'.

Moreover, you consider that ‘the release of the requested documents would enable the public to effectively participate in the legislative process, with the aim of improving the protection of human health and the environment and could provide further information as to why the legislative proposal on Food Information to Consumers was not released, and why its release is no longer included in the Commission’s work programme’.

You argue that ‘these specific circumstances - of the absence of release of the legislative proposal and of the non-inclusion of the latter in the Commission’s work programme, in addition with the essential principles of greater transparency, citizen participation in the decision making process as well as greater legitimacy, efficiency and accountability of the European administration towards citizens in a democratic system, undeniably establish the existence of an overriding public interest which justifies the release of the requested documents’. You also ‘refer to the general importance of the openness of decision making, of the Commission, which permits the public to participate in or even simply follow and understand decision making processes’.

In its *Turco v Council* judgment, the Court held explicitly that the overriding public interest capable of justifying the disclosure of a document covered by this exception must, as a rule, be distinct from the principles of transparency, openness, and democracy or of participation in the decision-making process¹³. The reason is that those principles are effectively implemented by the provisions of Regulation (EC) No 1049/2001 as a whole. In its judgment in the *Strack* case¹⁴, the Court of Justice ruled that in order to establish the existence of an overriding public interest in transparency, it is not sufficient to merely rely on that principle and its importance, but that an applicant has to show why in the specific situation at hand, the principle of transparency is in some sense especially pressing and capable, therefore, of prevailing over the reasons justifying non-disclosure¹⁵.

General references to the protection of human health are also insufficient to demonstrate the existence of an overriding public interest¹⁶, nor is the citizens' right to participate in decision-making¹⁷. The importance of the legislation regarding food information cannot be an overriding public interest that justifies disclosure of the documents at issue.

As regards the public interest into the matter, all stakeholders, including consumer and health organisations as well as the general public were consulted in the framework of the external study supporting the Commission’s impact assessment¹⁸. The consultation aimed to collect evidence and data for the analysis of the economic, social and environmental

¹³ Judgment of the Court of First Instance of 23 November 2004, *Maurizio Turco v Council of the European Union*, T-84/03, EU:T:2004:339, paragraphs 81-83.

¹⁴ Judgment of the Court of Justice of 2 October 2014 in case C-127/13 P, *Strack v Commission*, (EU:C:2014:2250), paragraph 128.

¹⁵ Judgment of the Court of Justice of 2 October 2014 in case C-127/13 P, *Strack v Commission*, (EU:C:2014:2250), paragraph 129.

¹⁶ Judgment of the Court of Justice of 11 May 2017 in case C-562/14 P, *Sweden and Spirlea v Commission*, paragraphs 56-57, EU:C:2017:356.

¹⁷ Judgment of the Court of Justice of 16 July 2015 in case C-612/13 P, *ClientEarth v Commission*, paragraph 93, EU:C:2015:486.

¹⁸ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12749-Food-labelling-revision-of-rules-on-information-provided-to-consumers_en

impacts of the policy options proposed for the different initiatives. A 12-week open public consultation was conducted between December 2021 and March 2022¹⁹ and extensive consultations with all stakeholders have been carried out.

Consequently, the considerations such as those indicated in your confirmatory application cannot provide an appropriate basis for establishing that the principle of transparency was in this case especially pressing and capable, therefore, of prevailing character over the reasons justifying the refusal to disclose the documents in question²⁰.

Nor has the Secretariat-General been able to identify any public interest capable of overriding the public and private interests protected by Article 4(3) of Regulation (EC) No 1049/2001.

4. PARTIAL ACCESS

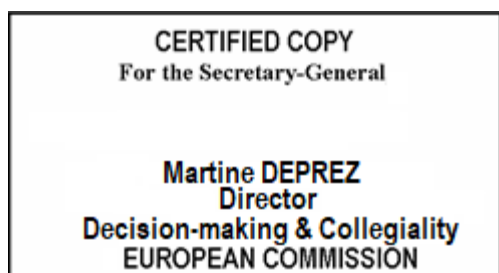
In accordance with Article 4(6) of Regulation (EC) No 1049/2001, the Secretariat-General has considered the possibility of granting partial access to the documents requested.

However, for the reasons explained above, no further meaningful partial access is possible without undermining the interests described above.

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 Articles 263 and 228 of the Treaty on the Functioning of the European Union.

Yours sincerely,



For the Commission
Ilze JUHANSONE
Secretary-General

¹⁹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12749-Food-labelling-revision-of-rules-on-information-provided-to-consumers/public-consultation_en

²⁰ Judgment of the Court of Justice of 14 November 2013, *Liga para a Protecção da Natureza (LPN) and Republic of Finland v European Commission*, Joined Cases C-514/11 P and C-605/11 P, EU:C:2013:738, paragraph 93.