

Reply of the European Commission to the proposal for a solution from the European Ombudsman regarding the European Commission's refusal to give public access to documents related to its proposal for a regulation on the European Health Data Space
- Complaint 1999/2022/SF

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

On 5 July 2022, the complainant submitted an initial application for access to documents under Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (hereafter 'Regulation (EC) No 1049/2001')¹.

The complainant requested access to '[a]ll documents related to the interservice consultation for the European Commission proposal for a Regulation on the European Health Data Space (COM(2022) 197 final)'.

The complainant's request was registered under reference GESTDEM 2022/3815 and handled at the initial level by the European Commission's Directorate-General for Health and Food Safety.

In its initial reply of 28 July 2022, the Directorate-General for Health and Food Safety identified 45 relevant documents. The Directorate-General for Health and Food Safety fully disclosed 7 documents²; partially disclosed 33 documents³; and withheld 5 documents⁴. The partial/full refusal was based upon the exceptions laid down in Article 4(1)(b) (protection of privacy), the third indent of Article 4(1)(a) (protection of international relations), the second indent of Article 4(2) (legal advice) and the first subparagraph of Article 4(3) (protection of the ongoing decision-making process) of Regulation (EC) No 1049/2001.

The confirmatory application submitted by the complainant on 10 August 2022 was expressly circumscribed to the five fully withheld documents which had been drafted in the framework of the Inter-Service Consultation concerning the European Health Data Space.

In its confirmatory decision of 24 November 2022, the European Commission granted partial access to the five documents in question, subject to the redaction of personal data on the basis of Article 4(1)(b) and of the parts protected under the exceptions laid down in the third indent of Article 4(1)(a) (international relations); the second indent of Article 4(2) (legal advice) and the first subparagraph of Article 4(3) (protection of the ongoing decision-making process) of Regulation (EC) No 1049/2001.

¹ OJ L 145 of 31.5.2001, p. 43.

² Namely documents 2.b; 3.b; 5.b; 8.b; 19.c; 21.b and 21.c.

³ Namely documents 1; 2.a; 3.a; 4.a to 5.a; 6 to 8.a; 9.a to 12.e; 14 to 19.b; 20.a and 21.a.

⁴ Namely documents 13.a; 13.b; 13.c; 13.d and 20.b.

II. THE COMPLAINT TO THE EUROPEAN OMBUDSMAN

Subsequent to the sending of the European Commission's confirmatory decision of 24 November 2022, the complainant contested before the European Ombudsman the partial access provided to documents 13a, 13b, 13c, 13d and 20b. According to the applicant, the redactions performed in these documents would not allow him to verify whether provisions that had been previously rejected by the European Commission's Legal Service have been reintroduced by the co-legislators. Moreover, the complainant argued that, without having seen the parts redacted, it was impossible for him to assess whether the European Commission was justified in refusing access based on the need to protect the public interest as regards the protection of international relations.

III. THE EUROPEAN OMBUDSMAN'S INQUIRY AND THE PROPOSAL FOR A SOLUTION

In the course of the European Ombudsman's inquiry, the European Commission provided to the latter a copy of the confirmatory decision, and the five documents requested by the applicant.

Following its inspection of these five documents, the European Ombudsman considers that the European Commission should review its position with a view to granting the widest possible public access to three of them (namely documents 13b, 13c and 20b) which were redacted (in addition to personal data pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001), under the exceptions laid down in the third indent of Article 4(1)(a) (international relations); the second indent of Article 4(2) (legal advice) and the first subparagraph of Article 4(3) (protection of the ongoing decision-making process) of Regulation (EC) No 1049/2001.

Where the European Commission considers that access cannot be granted, the European Ombudsman invites it to explain, in detail and with reference to the individual document/comment, how disclosure of each document/comment would undermine one or several of the public interests listed in Article 4 of Regulation (EC) No 1049/2001, if needed in a confidential annex.

IV. THE EUROPEAN COMMISSION'S POSITION ON THE PROPOSAL FOR A SOLUTION

The European Commission would like to stress that out of the 45 relevant documents identified as falling within the scope of the initial request of the applicant, seven documents were fully disclosed and 35 were widely released subject solely to the redaction of personal data in accordance with Article 4(1)(b) of Regulation (EC) No 1049/2001.

Only three documents, namely documents 13b, 13c and 20b, were further redacted based on the exceptions laid down in the third indent of Article 4(1)(a) (international relations); the second indent of Article 4(2) (legal advice) and the first subparagraph of Article 4(3) (protection of the ongoing decision-making process) of Regulation (EC) No 1049/2001.

Regarding Documents 13b and 13c

Document 13b is a six-page document entitled “Note of the Legal Service for the attention of Ms Sandra Gallina” of 4 March 2022, registered under Ares(2022)3507090. This note from the Commission Legal Service to the Director-General of the Directorate-General for Health and Food Safety sets out why the Legal Service issued a negative opinion on the draft proposal for the European Health Data Space Regulation during the interservice consultation.

Document 13c is the “Draft proposal with Track changes of the Legal Service” of 4 March 2022, registered under Ares(2022)3507090. The document contains questions, comments and drafting suggestions of the Legal Service on the Commission’s draft proposal for the European Health Data Space Regulation.

Concerning documents 13b and 13c, and the application of the exceptions concerning legal advice and protection of the ongoing decision-making process, a meeting took place on 4 May 2023 between the services of the European Ombudsman, on the one hand, and the European Commission departments, on the other hand.

It should be recalled that the Legal Service of the European Commission has a double function. First, it acts as in-house legal counsel in the internal decision-making process of the European Commission; second, it acts as the legal representative of the European Commission before the Union Courts. On that basis, this reply will set out why at this point in time, it is not possible to give full access to documents 13b and 13c. However, widest possible access to those documents will be granted immediately after the adoption of the Regulation on the European Health Data Space by Parliament and Council based on a new assessment by the Commission. At that point in time, the general principle will be access to the documents. The possible exception applicable would be very limited parts of the documents, for which the European Commission can show *in concreto*, based on the regulation as adopted by Parliament and Council, that the precise part of the document could be used in a possible future Court case brought against the legality of the regulation.

The specific role of the Legal Service of the European Commission

As mentioned, the Legal Service of the European Commission has a double function: first, it acts as in-house legal counsel in the internal decision-making process of the European Commission; second, it acts as the legal representative of the European Commission before the Union Courts.

The role of the Legal Service as in-house legal counsel

Article 21 of the Rules of Procedure of the European Commission⁵ provides that the Legal Service must always be consulted before initiating any of the procedures for the European Commission to adopt legal acts or proposals for legal acts.

⁵ OJ L 308, 8.12.2000, p. 26.

No legal act or proposal can be adopted by the European Commission in written procedure as long as the Legal Service has not given its agreement. As for the oral procedure, the Director-General of the Legal Service serves as *jurisconsulte* of the College of Commissioners, attends the meetings of the European Commission, and provides legal advice in the meetings of the European Commission, where requested to do so⁶. The detailed deliberations of the College of Commissioners, including the positions taken by the Legal Service, are not public, and the members of the College and the officials attending the meetings of the College are bound by the secret of the deliberations, in line with Article 9 of the Rules of Procedure of the Commission, which stipulates: ‘*Meetings of the Commission shall not be public. Discussions shall be confidential.*’

The main outcomes are published in the minutes of the College on the website of the European Commission, in the spirit of transparency.

According to the case-law of the Court of Justice, the public interest requires that the European Commission should be able to benefit from the advice of its legal service, given in full⁷. That advice should be “*frank, objective and comprehensive*”⁸. The Legal Service has the task, based on its role and particular knowledge, to provide the institution with all necessary information so that the institution adopts, in the exercise of its competences, legal acts that are in conformity with European Union Law.⁹

The role of the Legal Service as legal representative of the European Commission before the Union courts

The Legal Service has the monopoly to represent the European Commission before the Union courts. According to the case-law of the Court of Justice, the legal representative benefits from what is often referred to as “*legal privilege*”, i.e., it must be able to give advice to its client, without running the risk that that advice is divulged and then used against the client. More specifically, the Court of Justice has confirmed that the correspondence between the lawyer and his client is confidential, and the lawyer cannot be forced to divulge it. Otherwise, the right to a fair trial would be at risk¹⁰. This is also recognised in the case-law of the Court of Justice, concerning the interpretation of the second indent of Article 4(2) of Regulation (EC) No 1049/2001, which protects legal advice. Consequently, it is necessary to protect documents containing legal advice given by the Legal Service of the European Commission, when it is plausible that it may be confronted later in Court with its own assessment, given as in-house counsel of the European Commission, that an act of Union law

⁶ Paragraph 10–2 of the Rules giving effect to the Rules of Procedure, annexed to the European Commission’s Rules of Procedure, Decision C(2010)1200.

⁷ Standing case-law, see most recently Judgments of 16 February 2022, *Hungary v Parliament and Council*, C-156/21, EU:C:2022:97, paragraph 53, with further references; and of 16 February 2022, *Poland v Parliament and Council*, C-157/21, EU:C:2022:98, paragraph 50, with further references.

⁸ Judgment of 1 July 2008, *Sweden and Turco v Council*, C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 62.

⁹ Judgment of 2 June 2016, *Moises Bermejo Garde v Economic and Social Committee*, F-41/10 RENV, EU:F:2016:123, paragraph 67.

¹⁰ Judgment of 8 December 2022, *Orde van Vlaamse Balies*, C-694/20, EU:C:2022:963; paragraphs 25 to 28.

is illegal, in order not to impair its capacity to defend the legality of such an act.

The General Court held in *Philip Morris v Commission* that the protection of internal documents drawn up for the purposes of specific court proceedings is justified by the principles of equality of arms and the sound administration of justice¹¹. In other words, disclosure of an institution's position in ongoing court proceedings to another party could upset the balance between the parties to a dispute, in particular if only one party (the European Union institution) would have to disclose its position.

The purpose of that exception is precisely to prevent a situation where the Legal Service of the European Commission, when defending the legality of an act of Union law, could be confronted with its own assessment, given as in-house counsel of the European Commission, that that same act is illegal.

The European Ombudsman has recognised this principle in its decision concerning a refusal of the European Commission to grant access to opinions of the Legal Service¹².

The role of the Legal Service of the Commission in the preparation of the proposal for a Regulation on the European Health Data Space

The proposed Regulation on the European Health Data Space is at the cross-roads of two sensitive policy areas. On the one hand, it is about health, and personal health data, which is sensitive personal information. On the other hand, it is about the digitisation of that data, and the access to that data, and therefore on data protection and the right to privacy. The sharing of health data can provide opportunities for important medical innovation and strengthen the Union as a research area and provide important business opportunities. It can also improve the quality of medical services and reduce costs for health insurance providers. At the same time, that must be balanced against the right of citizens to privacy. The preparation of that proposal required the different European Commission services to explore many novel and complex political and legal questions, making full use of what is often termed their 'space to think'. The General Court has recognised the importance of preserving that space to think in its judgment in *Philip Morris v Commission*¹³. When the Legal Service was first consulted on an initial proposal, it had to issue a negative opinion, pointing out that the initial proposal, for a number of reasons, would not withstand a challenge before the Union courts, if the European Parliament and the Council were to adopt as such.

The Legal Service of the Commission issues a negative opinion exceptionally. It requires the prior information of the Director-General of the Legal Service. It sends a strong signal to the

¹¹ See the judgment of 15 September 2016 in case T-18/15, *Philip Morris Ltd v Commission*, EU:T:2016:487, in particular paragraph 64.

¹² Case 1920/2022/NH, Decision on how the European Commission dealt with a request for public access to documents concerning the adoption of EU rules on real driving emissions values, paragraphs 18 to 22.

¹³ See the judgment of 15 September 2016 in case T-18/15, *Philip Morris Ltd v Commission*, EU:T:2016:487, in particular paragraph 87; see also, by analogy, judgment of 12 March 2019 in case T-798/17, *De Masi and Varoufakis v ECB*, paragraphs 36 to 61, upheld on appeal in judgment of 17 December 2020, C-342/19 P, *De Masi and Varoufakis v ECB*, EU:C:2020:1035, paragraphs 48 to 53.

relevant European Commission services on the need to remedy the issues identified in the opinion.

The ordinary legislative procedure and the difference in roles between the Legal Services of the Commission, the Parliament and the Council

The transmission of the European Commission proposal to the European Parliament and the Council marks the starting point of the legislative process. The deliberations in the European Commission that precede the adoption and transmission of the proposal are, as already set out, confidential.

This changes radically in the subsequent steps, because the deliberations of the European Parliament and of the Council during the legislative process are public, according to Article 16(8) of the Treaty on European Union (TEU). As a result, also any intervention of the Legal Services of the European Parliament and the Council during those deliberations are public.

The Legal Services of the European Parliament and of the Council have the task of advising the European Parliament and the Council on any question that may arise during those deliberations. Indeed, the Members of Parliament and the delegations in the Council may ask for oral and written legal advice. This advice is given on a text which has been published by the European Commission, which has a defined scope and precise provisions, contrary to the various drafts and options examined by the European Commission Legal Service before the final text is submitted for adoption to the College taking its comments into account.

The Legal Service of the European Commission, on the contrary, has no self-standing role during the ordinary legislative procedure. Rather, it is only the European Commission, or the European Commission departments, who can make oral or written submissions to the European Parliament and the Council, but never the Legal Service of the European Commission in its function as Legal Service. This principle is important, because each institution has its own Legal Service, and each Legal Service has the exclusive prerogative of advising its own institution, but not the others.

The services of the European Ombudsman have also pointed out the role of the European Data Protection Board and the European Data Protection Supervisor. For certain pieces of legislation, the applicable rules provide that those bodies issue an opinion on the European Commission proposal. The reason why those opinions are issued is precisely to inform not only the decision-makers, but also the broader public of any potential risk for the protection of data that may result from the adoption of the legislation in question. The role of those bodies is hence precisely to inform the decision-making process of the European Parliament and the Council. The Legal Service of the European Commission, on the contrary, has no such role. For that reason, the case-law concerning access to legal opinions issued by the Legal Service of the Council during the ordinary legislative procedure cannot be extended by

analogy to legal opinions by the Legal Service of the European Commission prior to the beginning of the ordinary legislative procedure, precisely because the situation and role of the two Legal Services in an ordinary legislative procedure is different.

The complainant has clearly outlined the use he intends to make of the negative opinion of the Legal Service of the European Commission: he wants to use that opinion to put into doubt the legality of certain amendments that have been, or may in the future be proposed, to the proposal of the European Commission. The disclosure of the documents concerned would seriously undermine the role of the Legal Service of the European Commission in the legislative process.

A new actor would emerge, whose opinions would influence the legislative process alongside those of the Legal Services of the European Parliament and the Council, and advisory bodies such as the European Data Protection Board and the European Data Protection Supervisor. This would go against the institutional architecture of the legislative process.

The need to protect the negative opinion of the Legal Service of the Commission until the adoption of the Regulation on the European Health Data Space

The case at hand concerns, as already illustrated, a particularly sensitive case, where the Legal Service has issued – which it does very rarely – a so-called negative opinion. That indicates that the Legal Service considers that the text, as initially presented to the Legal Service, runs a very serious risk of censure by the Union courts, if it proceeds as it stands.

In the present case, the file is now in the ordinary legislative procedure and, as the European Commission will indicate in a confidential annex, amendments may be introduced which correspond to initial ideas from the European Commission services, and on which the Legal Service had advised against, or may raise the same or comparable legal problems.

Whether those amendments, or other ideas the substance of which the Legal Service had rejected, will eventually be included in text for a Regulation on the European Health Data Space, as adopted by the European Parliament and the Council, will only be known once that piece of legislation has been published in the Official Journal.

In view of the important societal impact and the very important economic risks at stake here, it is plausible that there will be legal challenges against the Regulation on the European Health Data Space. Those actions may either be brought, if the person is directly and individually concerned, before the European Union courts, or, in all other cases, before national courts, which then may or have to make a reference for interpretation and/or validity of the new rules.

The European Ombudsman has accepted in the past that the European Commission, in order to justify its decision not to disclose an Opinion of its Legal Service, needs to demonstrate that it is reasonable to expect that the issue discussed in the Opinion will likely come to

court¹⁴.

The European Commission considers that at this point of the ordinary legislative procedure, that standard is met, for the reasons set out in a confidential annex. The European Commission also reiterates that it will re-assess that finding once the European Parliament and the Council have adopted the Regulation on a European Health Data Space.

Regarding Document 20b

Document 20b is the “Reply of the Directorate-General for Trade” of 2 March 2022, registered under Ares(2022)3506436. It contains the comments and drafting suggestions of DG Trade on the Commission draft proposal for the European Health Data Space Regulation.

In the confirmatory reply, the European Commission invoked, the exceptions for the protection of legal advice, the ongoing decision-making process, and international relations in order to justify the redaction of four comments in Document 20b.

The European Commission has taken note of the European Ombudsman’s assessment of these exceptions and the opportunity to further explain how disclosure of these comments would undermine one or several of the public interests listed in Article 4 of Regulation (EC) No 1049/2001, if needed in a confidential annex.

On this basis, the European Commission would like to confidentially substantiate the motivation underlying the application of the exception for the protection of the public interest as regards international relations. In this regard, the European Commission wants to refer to settled case-law providing that it may be impossible to give the reasons justifying the refusal of access to each/part of document, without disclosing the content of the document or an essential aspect of it and thereby depriving the applicable exception/s of its/their very purpose¹⁵.

In this instance, the European Commission considers that any more complete and specific demonstration as regards the content of the redacted comments in document 20b could only jeopardise the confidentiality of information intended to remain out of the public domain, on the basis of the invoked exception laid down in the third indent of Article 4(1)(a) (international relations) of Regulation (EC) No 1049/2001.

Against this background, the European Commission is not in a position to provide further explanations to the applicant in addition to the already-detailed statement of reasons provided in the framework of its confirmatory decision.

¹⁴ Case 1920/2022/NH, Decision on how the European Commission dealt with a request for public access to documents concerning the adoption of EU rules on real driving emissions values, paragraph 22.

¹⁵ Judgment of 25 April 2005, *Sison v Conseil*, T-150/03, EU:T:2005:143, paragraph 84.

Nevertheless, as per the European Ombudsman's invitation, the European Commission submits further clarifications for the European Ombudsman's consideration as to the application of the international relations exception in a confidential annex.

IV. CONCLUSIONS

The European Commission has reviewed once more documents 13b and 13c on the basis of the criteria set out above. Based on a careful examination of all interests at stake, and in particular the proposal for a solution by the European Ombudsman and the meeting of 4 May 2023, the European Commission hereby grants wider access to those documents. It attaches the revised redacted versions of the documents in question, which will also be published on the Electronic Access to Commission Documents (EASE) portal.

At the same time, still for the reasons set out above, the European Commission cannot provide access to the parts of the documents which set out why certain initial ideas of the competent European Commission departments for a future Regulation on the European Health Data Space would be in violation of higher-ranking norms of EU law. That is because it cannot be excluded that those or on substance similarly problematic ideas may resurface again in the ordinary legislative procedure, and ultimately be included in the Regulation on the European Health Data Space, as adopted by the European Parliament and the Council.

In such a situation, it is plausible that legal challenges will take place. A confidential annex provides a detailed explanation of those risks.

The European Commission commits that it will revisit the matter as soon as the European Parliament and the Council adopt the Regulation on the European Health Data Space. At that point in time, the general principle will be full access to documents 13b and 13c. The only possible exception would be very limited parts of the documents, for which the Commission can show *in concreto*, based on the regulation as adopted by Parliament and Council, that the precise part of the document could be used in a Court case brought against the legality of the regulation to contest the legality of the regulation.

No later than one month after the adoption of the Regulation on the European Health Data Space, the European Commission will inform the European Ombudsman on the outcome of that reassessment and, if applicable, disclose, on its own motion, documents 13b and 13c, subject to the caveat that very limited redactions may still be required if the risk materialises that one of the ideas which the Legal Service of the European Commission considered in violation of higher-ranking norms of EU law is included in the text as finally adopted by the European Parliament and the Council.

The European Commission has also reviewed again document 20b and has decided to further clarify the motivation provided in the confirmatory reply regarding the application of the exception for the protection of the public interest as regards international relations. Considering that these clarifications reveal elements that would affect the European Union

strategic objective and confidential positions in negotiations with third countries, it is presented to the European Ombudsman in a confidential annex. For the reasons stated in the confirmatory reply and further clarified in a confidential annex, the European Commission considers that it cannot grant wider access to document 20b than that granted in the confirmatory reply.

The European Commission understands that the European Ombudsman will communicate to the complainant the present reply and the redacted version of documents 13b and 13c, which will also be published on the Electronic Access to Commission Documents (EASE) portal.

Moreover, the European Commission understands that the confidential annexes will not be transmitted to the complainant. The clarifications contained in the confidential annexes, which are provided following the European Ombudsman's invitation, are not to be construed as a supplementary justification which ought to be provided to the applicant in the framework of either the contested confirmatory decision, or as a result of the present inquiry.

For the Commission

Janusz WOJCIECHOWSKI

Member of the Commission

