



EUROPEAN COMMISSION

Brussels, 11.7.2025  
C(2025) 4910 final

Ms Vicky Cann

**DECISION OF THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 11 OF THE  
DETAILED RULES FOR THE APPLICATION OF REGULATION (EC) NO 1049/2001,  
ANNEXED TO THE RULES OF PROCEDURE OF THE COMMISSION<sup>1</sup>**

**Subject: Your confirmatory application for access to documents under  
Regulation (EC) No 1049/2001 – EASE 2023/5658**

Dear Ms Cann,

I refer to your email of 01 November 2023, registered on 06 November 2023, by which you submitted a confirmatory application in accordance with Article 7(2) of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents<sup>2</sup> (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 28 September 2023, addressed to the Secretariat-General and attributed to the Regulatory Scrutiny Board (RSB), you requested access to, I quote,

‘- any impact assessments on the Reach revision submitted to the Regulatory Scrutiny Board (RSB)

- all RSB opinions on these impact assessments.’

In its initial reply of 18 October 2023, the Regulatory Scrutiny Board stated that you had requested the same set of documents in your request for access to documents registered under reference EASE 2022/6860.

---

<sup>1</sup> Commission Decision (EU) 2024/3080 of 4 December 2024 establishing the Rules of Procedure of the Commission and amending Decision C(2000) 3614 (OJ L, 2024/3080, 5.12.2024, ELI: <http://data.europa.eu/eli/dec/2024/3080/oj>).

<sup>2</sup> Official Journal L 145 of 31.5.2001, p. 43.

It outlined the conclusions of the assessment carried out by the European Commission in the handling of the above-mentioned request both at initial and at confirmatory level and referred you to these decisions.

In your confirmatory application, you request a review of this position. You refer to a recommendation by the European Ombudsman from September 2023 (case 1053/2023/MIK)<sup>3</sup> and cite the judgment by the Court of Justice in case C-57/16<sup>4</sup>. You underpin your request with detailed arguments, which will be addressed in the corresponding sections 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 service at the initial stage.

It is only in view of changed factual or legal circumstances that the Commission is required to re-assess a request for documents that had been subject to a previous request<sup>5</sup>. Indeed, in the timeframe between the confirmatory decision in case EASE 2022/6860 and the submission of the confirmatory application in the case at hand, EASE 2023/5658, the ownership of the studies cited in the decision in case EASE 2022/6860 has been acquired by the Commission, representing a change in factual and legal circumstances and thus requiring a renewed assessment of the request. Therefore, the Secretariat-General has conducted a review of your request in light of the changed circumstances.

The following documents have been identified as falling under the scope of your request:

- The draft impact assessment submitted to the Regulatory Scrutiny Board on 12 October 2022, reference Ares(2022)7059954 (hereafter ‘document 1’), containing the following annexes:
  - Annexes to the draft impact assessment (hereafter ‘document 1.1’);
- The opinion of the Regulatory Scrutiny Board on the impact assessment, reference Ares(2022)7982198 (hereafter ‘document 2’).

Please note that these documents are identical to the documents identified in case EASE 2022/6860, to which you have been granted partial access. No new documents falling under the scope of your request have been produced in the meantime.

---

<sup>3</sup> Please see <https://www.ombudsman.europa.eu/en/recommendation/en/175628>.

<sup>4</sup> Judgment of the Court of Justice of 4 September 2018, *ClientEarth v Commission*, C-57/16 P, EU:T:2018:660.

<sup>5</sup> Judgment of the Court of Justice of 26 January 2010, *Internationaler Hilfsfonds v Commission*, C-362/08, EU:C:2010:40, paragraph 57.

Following the review by the Secretariat-General, I regret to inform you that no further access can be granted to the documents identified, as further disclosure is prevented by the exception to public access to documents as enshrined in the first subparagraph of Article 4(3) of Regulation (EC) No 1049/2001 (protection of the ongoing decision-making process), for the reasons set out below.

### **2.1. Protection of the ongoing 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.’

The documents requested are the draft Impact Assessment for the revision of the Regulation on the registration, evaluation, authorisation and restriction of chemicals (REACH) (hereinafter ‘REACH Regulation’) and its annexes, submitted to the RSB on 12 October 2022, and the opinion of the RSB on the submitted impact assessment.

In your confirmatory application, you refer to the Ombudsman recommendation in case 1053/2023/MIK<sup>6</sup>. You state that, I quote, ‘[t]he Commission should either have immediately responded positively to the Ombudsman's recommendation and released the documents in response to my request, or at least left open my request via extended time limits (which is very common practice when handling access to document requests) in case the Commission's "examination" of the Ombudsman's recommendation leads to the conclusion that the documents should indeed be released.’

Please note that in its detailed reply to the recommendation<sup>7</sup> issued by the European Ombudsman, the Commission maintained its position set out in its confirmatory reply in case EASE 2022/6860. This position and its underlying considerations as regards the applicability of Article 4(3) of Regulation (EC) No 1049/2001, are still relevant and valid for the decision at hand.

The REACH Regulation was adopted in 2006 to ensure a high level of protection of human health and the environment, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. A revision was announced as part of the European Commission’s Chemicals Strategy for Sustainability<sup>8</sup>. The European Commission proposal for the revision of the REACH Regulation was included in the Commission Work Programme 2023 for adoption by the fourth quarter of 2023.

---

<sup>6</sup> Please see <https://www.ombudsman.europa.eu/en/recommendation/en/175628>.

<sup>7</sup> Please see attached the publicly available version of the reply published in EASE portal.

<sup>8</sup> Communication from the commission to the European parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2020) 667 final, 14.10.2020.

As Executive Vice-President Šefčovič pointed out in his reply to the European Parliament on 4 October 2023, the European Commission's preparations will continue in 2024 on the targeted amendment of the REACH Regulation to protect human health and the environment and foster competitiveness and innovation for substitution.

The revision of the REACH Regulation has attracted intense attention from different stakeholders and extensive media coverage<sup>9</sup>. The work for its development has been carried out in a transparent manner, including involving all relevant stakeholders in public and targeted consultations and discussions. All interested stakeholders were given the possibility to contribute to the decision-making process via these extensive consultations, which included:

- a four-week feedback period on the publicly available inception impact assessment (from 4 May to 1 June 2021);
- a 12-week public consultation, available to all stakeholders in all the EU official languages and published on the 'Have Your Say' website<sup>10</sup>;
- a five-week SME panel questionnaire (from 31 March to 6 May 2022) to reach SMEs in a targeted way, with the help of the European Enterprise Network;
- as part of technical support studies, 10 workshops<sup>11</sup>, seven targeted surveys and 164 interviews (indicatively from end of 2021 until mid-2022);
- regular meetings of the Competent Authorities for REACH and CLP expert working group (CARACAL), attended by Member State Competent Authorities and accredited stakeholder organisations, representing civil society as well as trade associations and companies<sup>12</sup>.

It should be noted that as per the Better Regulation guidelines and toolbox, Commission proposals adopted by the College are published and subject to an eight-week feedback mechanism, which gives yet another opportunity to stakeholders to express their views and contribute to the decision-making process.

---

<sup>9</sup> See, for example, Kurmayer N., 31 January 2024, Euractiv, [PFAS: Brussels top brass found to have 'forever chemicals' in their bloodstream – Euractiv](#) (accessed on 8 March 2024).

<sup>10</sup> Please see [Chemicals legislation – revision of REACH Regulation to help achieve a toxic-free environment \(europa.eu\)](#).

<sup>11</sup> The workshops revolved around these topics: information requirements on use and exposure, registration of polymers, Derived Minimal Effect Level for non-threshold substances, introduction of Mixtures Assessment Factors, reforming the restriction and authorisation processes, extending the generic approach to risk management, the essential use concept, and integration of REACH into customs legislation and procedures.

<sup>12</sup> The European Commission gave a comprehensive overview of the progress with the revision of the REACH Regulation at the open session of the CARACAL meeting on 28 March 2023.

In addition, the unredacted parts of the documents requested, in particular in the draft Impact Assessment, and previously published studies<sup>13</sup> conducted in the context of the revision of the REACH Regulation, allow an extensive understanding of the available policy options and the considerations and consequences underlying each of these options. Therefore, citizens are in a position to make their views known vis-à-vis their preferred option, even before the documents relating to the Impact Assessment are, in line with established practice, published once a decision has been taken.

The Court of Justice held that if the Commission is of the view that full access cannot be granted to a document drawn up in the context of an Impact Assessment, it will have to establish that disclosure would create a serious risk undermining its decision-making process. Such a risk depends on factors such as the state of completion of the document in question and the precise stage of the decision-making process at stake at the time when access to that document is refused, the specific context in which that process takes place, and the issues still to be discussed internally by the institution concerned<sup>14</sup>.

In addition, in the recent judgement in case T-163/21, the General Court confirmed that EU primary law does not provide for an unconditional right of access to legislative documents, but that this right is to be exercised in accordance with the general principles, limits and terms determined by means of regulations. Article 15(3) Treaty on the Functioning of the European Union does not exclude legislative documents from its scope<sup>15</sup>.

The redacted passages of the draft Impact Assessment contain information about the possible impacts of policy options, a comparison of the options, details on a preferred option and the methodology for evaluating impacts. The redactions in the annexes regard details of the potential options, the practical implications of proposed options of the initiative and the methodology for screening and assessing impacts. In the RSB opinion, redactions regard the overall opinion of the Board, the summary of the findings, which mirror the information in the draft Impact Assessment, the conclusion, as well as the detailed comments on the draft Impact Assessment.

---

<sup>13</sup> Finalised and published studies:

- Study on the establishment of a European audit capacity to ensure compliance and effective national control and enforcement of the REACH regulation and on the extension of that capacity and of those standards to CLP, POPs and PIC regulations, <https://data.europa.eu/doi/10.2779/951>.
- Gather further information to be used in support of an impact assessment of potential options, for the update of REACH annexes for inclusion of data requirements on endocrine disruption, <https://data.europa.eu/doi/10.2779/90611>.
- Gather further information to be used in support of an impact assessment of potential options, in particular possible amendments of REACH Annexes, to modify requirements for registration of low tonnage substances (1-10t/year) and the CSA/CSR requirement for low tonnage substances with or without CMR properties in the framework of REACH, <https://data.europa.eu/doi/10.2779/37609> (final report) and <https://data.europa.eu/doi/10.2779/691128> (annex).
- Study to support the integration of REACH aspects into customs legislation and procedures, <https://data.europa.eu/doi/10.2873/624540>.
- Supporting the Commission in developing an essential use concept, <https://data.europa.eu/doi/10.2779/529713>.

<sup>14</sup> Judgment of the Court of Justice of 4 September 2018, *ClientEarth v Commission*, C-57/16 P, EU:T:2018:660, paragraph 111.

<sup>15</sup> Judgment of the General Court of 25 January 2023, *De Capitani v Council*, T-163/21, EU:T:2023:15, paragraph 39, 46.

The Commission submitted the draft Impact Assessment to the RSB for its opinion on 12 October 2022. While the Board delivered its opinion on 18 November 2022, the draft Impact Assessment is still being revised following the substantial recommendations received. The Commission services are still analysing the opinion of the Board and are considering changes to the draft impact assessment, especially for parts relating to the problem definition (section 2), the assessment of impacts, including the on cost and benefit estimates (section 6), the comparison of options (section 7) and the analysis, proportionality, and choice of the preferred package of options (section 8). As the Commission has not yet taken a decision on this, the decision-making process is not completed but fully ongoing.

Indeed, internal considerations, the new Commission's political guidelines, changes to accommodate the Board's opinion 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 included in the legislative proposal. The agreed preferred options will be introduced in the Commission proposal subject to the ordinary legislative procedure for the elements requiring changes to the enacting terms of REACH, and by a comitology act for the changes to the REACH Annexes (requiring a positive vote by the REACH Committee on the Commission proposal). Thus, until there is a final decision on the preferred options, all elements of the revision of the REACH Regulation are susceptible to change.

Due to ongoing consultations and internal negotiations, the announced review of the REACH Regulation was postponed, heightening the pressure on all actors involved and making the negotiations more sensitive, especially given the intensive media coverage and lobbying efforts from different sides<sup>16</sup>.

If released now, the content of the redacted parts of the Impact Assessment, its annexes, and the RSB opinion would give rise to unwanted external pressure by various stakeholders who have an interest in this process, outside the framework of the stakeholders' consultations that the Commission has already been actively engaging in to ensure that all views are heard and taken into account. Therefore, this would seriously undermine the ongoing decision-making process. It would subject the ongoing work on the revision of the REACH Regulation to further unnecessary pressure from stakeholders because of the different perceptions and views on the expected impacts for companies, the additional needs of animal tests, and the expected impacts for human health and the environment. This would, in turn, undermine the administrative capacities that need to deliver the Commission proposal, putting at risk its adoption.

---

<sup>16</sup> For instance: Romano V., Euractiv, 19 February 2023, <https://www.euractiv.com/section/chemicals/news/game-over-for-eus-reach-chemical-safety-review-campaigners-say/> (access on 8 March 2024). Finke, B., Süddeutsche Zeitung, 24 August 2022, [Überlastet Brüssel Europas Firmen? - Wirtschaft - SZ.de \(sueddeutsche.de\)](https://www.sueddeutsche.de/wirtschaft/ueberlastet-bruessel-europas-firmen?from_search_results=true) (access on 25 July 2024).



Indeed, as the General Court has held, ‘the possibility of expressing views independently within an institution helps to encourage internal discussions with a view to improving the functioning of that institution and contributing to the smooth running of the decision-making process’<sup>22</sup>.

This is particularly relevant as the file is still being discussed, partly at highest level, involving many actors. Discussions on the different parts of the proposal, which are based on the Impact Assessment, have been ongoing between the relevant Commission Services responsible for the REACH Regulation, including exchanges at senior management level where appropriate.

Considering the precedents of lobbying influence, the current stage of the decision-making process and its specific context, as well as the issues still to be discussed internally, disclosure of the redacted parts of the requested documents would seriously undermine the preparation of the proposal and the Commission’s decision-making process. Divulging the redacted parts of the study risks feeding more misunderstandings, as those caused by the premature divulgation of leaked information by LeMonde and The Guardian.

Therefore, disclosure of the redacted information 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 withheld parts of the three documents identified above would bring a serious harm to the decision-making process concerned.

In light of the above, the Secretariat-General concludes that the redacted parts 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 the first subparagraph of 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. It is for the applicant to put forward specific circumstances that show that there is an overriding public interest, which justifies the disclosure of the documents concerned<sup>23</sup>.

---

<sup>22</sup> Judgment of the General Court of 15 September 2016, *Phillip Morris v Commission*, T-18/15, EU:T:2016:487, paragraph 87.

<sup>23</sup> See e.g. judgment of the General Court of 5 December 2018, *Liam Campbell v European Commission* T-312/17, EU:T:2018:876, paragraph 58; Judgment of the General Court of 1 February 2023, *ClientEarth v Commission*, T-354/21, EU:T:2023:34, paragraph 92.

According to the case-law, the applicant must, on the one hand, demonstrate the existence of a public interest likely to prevail over the reasons justifying the refusal of access to the documents concerned and, on the other hand, demonstrate precisely in what way disclosure of the documents would contribute to assuring protection of that public interest to the extent that the principle of transparency takes precedence over the protection of the interests which motivated the refusal<sup>24</sup>.

In your confirmatory application, you do not mention any overriding public interest in the disclosure of the documents requested.

In this regard, please note that the Court of Justice ruled in the *Strack* case<sup>25</sup> 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-disclosure<sup>26</sup>.

The Secretariat-General assessed whether there is an overriding public interest justifying the disclosure of the documents concerned. According to case-law, in legislative files, the overriding public interest test should result in wider openness<sup>27</sup>. However, there is not an unconditional right of direct access to any impact assessment documents, but an individual assessment of the request for access still has to be made for each document drawn up in the context of an impact assessment<sup>28</sup>. In this case, an individual assessment was carried out and for the reasons stated above, the Secretariat-General has not been able to identify any public interest capable of overriding the interests protected by first subparagraph of Article 4(3) of Regulation (EC) No 1049/2001.

Therefore, not having been able to identify any public interest capable of overriding the interest protected by the first subparagraph of Article 4(3) of Regulation (EC) No 1049/2001, the Secretariat-General concludes that an overriding public interest has not been demonstrated in this particular case.

---

<sup>24</sup> Judgment of the General Court of 9 October 2018, *Anikó Pint v European Commission*, T-634/17, EU:T:2018:662, paragraph 48; Judgment of the General Court of 23 January 2017, *Association Justice & Environment, z.s v European Commission*, EU:T:2017:18, paragraph 53; Judgment of the General Court of 5 December 2018, *Falcon Technologies International LLC v European Commission*, T-875/16, EU:T:2018:877, paragraph 84.

<sup>25</sup> 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.

<sup>26</sup> 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.

<sup>27</sup> Judgment of the Court of Justice of 1 July 2008 in case C-39/05 P and C-52/05 P, *Sweden & Turco v Council*, paragraphs 44-46.

<sup>28</sup> Judgment of the Court (Grand Chamber) of 4 September 2018 in case C-57/16 P, *ClientEarth v European Commission*.

#### **4. PARTIAL ACCESS**

In accordance with Article 4(6) of Regulation (EC) No 1049/2001, the Secretariat-General has considered the possibility of granting further 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 bring proceedings before the General Court and/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*

