Subject: Your confirmatory application for access to documents under Regulation (EC) No 1049/2001 – 2022/5960

Dear Ms Roger,

I am writing in reference to your confirmatory application registered on 8 February 2023, submitted in accordance with Article 7(2) of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (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 19 October 2022, handled by the Directorate-General for Environment, you requested access to ‘access to documents prepared in the context of the legislative initiative regarding REACH (This initiative is mentioned and described at: https://ec.europa.eu/environment/chemicals/reach/reach_revision_chemical_strategy_en.htm ). The documents requested consist of:

a) any impact assessment report(s) whether in draft form or already finalized; and

b) any opinion(s) by the Regulatory Scrutiny Board (RSB) on the impact assessment report(s), as soon as issued’.

The European Commission identified the following documents as falling under the scope of your request:

- Commission staff working document draft impact assessment report Accompanying the document Proposal for a Regulation of the European

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Parliament and of the Council Amending Regulation (EC) No 1907/20062 (hereafter document 1);

In its initial reply of 18 January 2023, the Directorate-General for Environment granted partial access to these documents with redactions based on the exceptions of the first subparagraph of Article 4(3) (protection of the decision-making process) of Regulation (EC) No 1049/2001.

In your confirmatory application, you request a review of this position. 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 Directorate-General concerned at the initial stage.

As a preliminary step, the Secretariat-General would like to clarify certain aspects related to the scope of your request. In point II of your request, you ask the Commission to, ‘(i) verify the existence of the Requested RSB Opinion and grant full access to it, should the document exist– as the lack of any information on this document in the Decision amounts to failure to state reasons under Article 289 TFEU’. You argue that the initial reply does not give any information in relation to the Requested RSB Opinion, despite your express request for its disclosure.

Please note that your initial request was registered on 19 October 2022. At this date, the Regulatory Scrutiny Board (hereafter ‘RSB’) had not issued any opinion, either in final or in draft form, on the draft impact assessment and hence, such a document was non-existent. Contrary to what you argue in your confirmatory application, notably that the lack of any information on this document in the Decision amounts to failure to state reasons under Article 289 TFEU, I note that the initial reply clearly stated that it considers that your request covers documents held up to the date of your application, i.e. 19 October 2022.

Finally, in your confirmatory application you note that ‘in case the Decision is to be understood as meaning that at the time of the request (i.e. on 19 October 2022), the requested RSB Opinion did not exist, and for that reason this document was considered

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to not fall within the scope of the present Request, we urge the Commission to disclose them now with the confirmatory decision, and note that the Commission is entitled to do so, in line with paragraph 84 of the Court’s judgment in case T-635/16 Malta v Commission and in light of Article 41 of the Charter of Fundamental Rights of the EU. In the alternative, we would kindly request the Commission to treat this confirmatory application as a new request to the RSB Opinion on the Impact Assessment Reports concerning the REACH revision (i.e. the Requested RSB Opinion) that has started to exist since then (i.e. between 19 October 2022 and 8 February 2023).’

Please note that a new initial request for the above-mentioned document (opinion of the RSB) has been registered and attributed for handling to the Directorate-General for Environment.

Following the review of the documents falling within the scope of the confirmatory application, I can inform you that I have to confirm the initial decision of the Directorate-General for Environment to refuse further access, based on the exceptions of Article 4(2) first indent (protection of the commercial interests, including intellectual property) 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 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 consider that in ‘[i]n the overall justification, the Commission is also relying on the CJEU case C-57/16, ClientEarth v. Commission. This is particularly remarkable as in that case, the Court actually ruled the contrary to the conclusions of the Commission in the Decision. The Court concluded that documents drawn up in the context of an impact assessment for a possible legislative proposal, including draft and final impact assessment reports and the opinions of the RSB, represent legislative documents. In this context, the Commission is obliged to make them directly accessible to the public pursuant to Article 12(2) of Regulation No 1049/2001 and that access should not be denied when such are requested.’

In this context, please note that the judgment in the case *ClientEarth* referred to above does not procure an unconditional right of direct access to any impact assessment documents but indicates that 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.

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, 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. 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, which is exercised instead in accordance with the general principles, limits and terms determined by means of regulations. Article 15(3) TFEU does not exclude legislative documents from its scope.

In the present case, contrary to what you argue in your confirmatory application, the Commission has not applied a general presumption of non-disclosure to the documents, but has performed an individual and concrete assessment, which resulted in granting partial access to the documents. That interpretation is consistent with Article 52(2) of the Charter of Fundamental Rights of the EU, according to which rights recognised by the Charter for which provision is made in the Treaties are to be exercised under the conditions and within the limits defined by those Treaties.

The principle of openness, although of fundamental importance to the EU legal order, is not absolute and, consequently, it remains open to the EU institutions to refuse, on the basis of the first subparagraph of Article 4(3) of Regulation No 1049/2001, to grant access to certain documents of a legislative nature in duly justified cases.

The REACH regulation was adopted in 2006 to protect human health and the environment from adverse effects of chemicals. A revision was announced as part of the Commission’s Chemicals Strategy for Sustainability. The Commission proposal for the revision of the REACH Regulation is currently set to be adopted by the fourth quarter of 2023. The revision of the regulation has attracted attention from different stakeholders. The work for its development has been carried out in a transparent manner, involving all relevant stakeholders, including ClientEarth, in public and targeted consultations and discussions. Studies for the purpose of developing the impact assessment have been carried out and within their context, further public consultations were performed. The majority of the

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5 Ibid, paragraph 43.
6 Ibid, paragraphs 56 and 57.
7 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.
studies which have been finalised and which feed into the draft impact assessment, are already public\(^8\).

However, the requested impact assessment is only a draft version. In view of the time pressure, the Commission’s services’ work on presenting a proposal is currently ongoing. The draft impact assessment to be submitted for adoption to the College of Commissioners together with that proposal is yet not finalised as the Commission services responsible need to analyse all input received.

The Commission submitted the draft impact assessment to the Regulatory Scrutiny Board for its opinion on 12 October 2022. While the Board delivered its opinion on 18 November 2022, it is still being revised throughout following the substantial recommendations therein. The Commission services are currently still analysing the opinion of the Board and are considering changes to the draft impact assessment, for instance relating to the parts concerning the choice and impact analysis of key policy options, the analysis of impacts, including on cost and benefit estimates, competitiveness and SMEs, as well as the analysis, proportionality, and choice of the preferred package of options. As the Commission has not yet taken a decision on this, the decision-making process is not completed and is fully ongoing.

Concretely, 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 the following: amendments of information requirements in the registration dossiers; the identification and registration of polymers; the fundamental elements and the details of the reform of the authorisation and restriction process; and the policy options for the strengthening of Member States’ official control systems for chemicals. Until there is a final agreement on the preferred option, all issues, even those agreed, are susceptible of being re-opened.

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 included in the legislative proposal. The agreed preferred options will be implemented via the ordinary legislative procedure for the elements requiring changes to the enacting terms of REACH and by a comitology act.

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\(^8\) Finalised and published studies:

for the changes to the REACH Annexes (requiring a positive vote by the REACH Committee on the Commission proposal).

If released now, the content of the redacted parts could give rise to unwanted external pressure by various stakeholders who have an interest in this process, thus seriously undermining the decision-making process. It would subject the ongoing work on the REACH revision (scheduled in the Commission Work Programme for adoption by the end of 2023) to further unnecessary pressure, undermining the administrative capacities that need to deliver the Commission proposal and putting at risk its timely adoption. Considering the state of completion of the documents 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 redacted parts of the requested documents would seriously undermine the preparation of the proposal and the Commission decision-making process. Specific sentences in the redacted parts could be taken out of context, affecting the conduct of the ongoing decision-making process.

Indeed, the revision of REACH will have significant impacts on a wide range of stakeholders, including significant costs for the chemical industry and its downstream users, potential gains for certain industry groups, impact on the environment, animal testing, and public health. In this context, industry, environmental NGOs, or animal welfare organisations, can try to influence the decision-making process. Such lobbying in the context of the REACH revision and of the related Chemicals Strategy for Sustainability has already been documented in the press⁹. Therefore, the risk is concrete and not hypothetical. As Commission services are still working on the file, they must be free to explore all possible options without constraint in preparation of the decision.

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.

Please note that the jurisprudence of the Union Courts has recognised that the capacity of the staff of the institutions to express their opinions freely must be preserved, to avoid the risk that disclosure would lead to future self-censorship. 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’¹⁰.

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

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In light of the above, the Secretariat-General concludes that the parts of documents 1 and 2 concerned 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.

2.2. Protection of the commercial interests

The first indent of Article 4(2) of Regulation (EC) No 1049/2001 provides that ‘[t]he institutions shall refuse access to a document where disclosure would undermine the protection of […] commercial interests of a natural or legal person, including intellectual property […], unless there is an overriding public interest in disclosure’.

In accordance with the case-law of the Court of Justice, ‘a European Union institution may take into account cumulatively more than one of the grounds for refusal set out in Article 4 of Regulation No 1049/2001 when assessing a request for access to documents held by it’¹¹. Accordingly, the exceptions relating to the protection of commercial interests and of the decision-making process are, in the present case, closely connected.

As the Court of Justice explained, ‘in order to apply the exception provided for by the first indent of Article 4(2) of Regulation No 1049/2001, it must be shown that the documents requested contain elements which may, if disclosed, seriously undermine the commercial interests of a legal person’¹². Furthermore, the Court of Justice recognised that, ‘[i]n order that information be of the kind to fall within the ambit of the obligation of professional secrecy, it is necessary, first of all, that it be known only to a limited number of persons. It must then be information whose disclosure is liable to cause serious harm to the person who has provided it or to third parties. Finally, the interests liable to be harmed by disclosure must, objectively, be worthy of protection. The assessment as to the confidentiality of a piece of information thus requires the legitimate interests opposing disclosure of the information to be weighed against the public interest that the activities of the Community institutions take place as openly as possible’¹³.

As explained in the section above, both the draft Impact Assessment and Annex are based on various studies conducted by contractors. These studies result from the conclusions of contracts between the European Commission with consultants. The European Commission acquires ownership of these studies, as from the moment the contractor has finalised the studies. This results from the General Conditions of the framework contract for services No ENV.B.2/FRA/2020/0010 “Scientific and technical assistance for the implementation of chemicals legislations on REACH, CLP, PIC and POPs”¹⁴, and more specifically Article II.13.1 thereof, concerning the ownership of the

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rights in the results. This Article provides that the Union acquires irrevocably worldwide ownership of the results, defined in Article II.1 as any intended outcome of the implementation of the framework contract, whatever its form or nature, and of all intellectual property rights on the newly created materials produced specifically for the Union under the framework contract and incorporated in the results. It is further specified in Article II.13.1 that “The Union acquires all the rights as from the moment the contractor has created the results”. These results in the case in hand are precisely the final reports. As provided in Article I.6.3 “Payment of the balance” of the Special Conditions, the contractor must send an invoice for payment of the balance due, and accompanied by a list of all pre-existing rights to the results or parts of the results or a declaration stating that there are no such pre-existing rights, as well as a final report and deliverable(s) in accordance with the relevant specific contract. It is further specified that “the contracting authority must approve the submitted documents or deliverables and pay within 60 days from receipt of the invoice”.

From the provisions of the contract, it can be deduced that the contractor may only claim the final payment if he has submitted the final report and the declaration on pre-existing rights. A contract ends when both parties have fulfilled their obligations. If the results are not approved, no payment is executed, and the contract is not finished.

Please note that not all the studies have been finalised yet. In fact, the redacted parts in the documents contain information from non-finalised as well as unpublished studies. The contractors are still the owners of studies that have not been finalised. The exchanges between the services of the Commission responsible and the consultants on the remaining issues are still ongoing. This concerns, for instance, the sections of the report related to the generic approach to risk management (for which the related study has not been finalised yet).

Copyright is an intellectual property right, which grants rights by way of legal protection to the authors of a work. This includes documents of any nature where the conditions for originality are met. Only the author can authorise or prohibit its dissemination.

As held by the General Court in its judgment in Case T-185/19, ‘[…] it follows from the Court’s settled case-law on the interpretation of the autonomous concept of ‘work’ that, if a subject matter is to be capable of being regarded as original, it is both necessary and sufficient that the subject matter reflects the personality of its author, as an expression of his or her free and creative choices’.

Consequently, the Secretariat-General considers that the use of the exception under the first indent of Article 4(2) (protection of commercial interests) of Regulation (EC) No 1049/2001 is justified, and that access to the specific parts of the documents pertaining to non-finalised studies must be refused on that basis.

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Consequently, the Secretariat-General considers that the use of the exceptions under the first indent of Article 4(2) (protection of commercial interests) and the first subparagraph of Article 4(3) (protection of the decision-making process) of Regulation (EC) No 1049/2001 is justified, and that access to the redacted parts of the documents must be refused on that basis.

3. **OVERRIDING PUBLIC INTEREST IN DISCLOSURE**

The exception laid down in Article 4(2) and 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 request, you consider that the request documents ‘also contain environmental information within the meaning of Article 2(1)(d) of Regulation 1367/2006.’ You further consider that there is an overriding public interest in disclosing the documents requested.

You claim that ‘[t]he specific circumstances of this case are such that the need for the public to have full access to the requested documents at the current moment is so pressing as to justify their disclosure. As recalled in the Inception Impact Assessment on the Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislationrevision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en]: “The objectives of the Chemicals Strategy for Sustainability are to better protect citizens and the environment against hazardous chemicals and encourage innovation for the development of safe and sustainable alternatives. To this end the Strategy outlined a number of actions intended to increase the knowledge base and control of chemicals. Chemicals are everywhere in our daily lives. They are fundamental for our well-being and high living standard and are important building blocks of key technologies to address future challenges. […] The REACH Regulation was last evaluated in 2018 (referred to as “latest REACH Review” below). It concluded that REACH is effective but that there are opportunities for further improvement, simplification and burden reduction. Following the evaluation, a number of non legislative actions have been launched (some of them finalised, others still ongoing) to improve the implementation of REACH. There is no doubt that this initiative is of public interest as it should reduce the risk that products and services put on the EU market and "will increase the protection of human health by reducing the exposure to hazardous chemicals, for citizens in general, and for workers and self-employed, including via the environment" (according to the Inception Impact Assessment). This upcoming legislation will apply across sectors and therefore should have an effect on all businesses operating in the EU. As business activities impact people and the environment, the Applicant consider that the consequences of the choice of the legislative instrument are crucial for the objective of getting a more sustainable and less harmful economy and should therefore be examined at all stages of the decision making process.'
This last point also reveals that an overriding public interest in disclosure exists. According to the parts disclosed of the Impact Assessment (section 3.1): “[t]he revision of REACH is harmonising provisions on chemicals at EU level to preserve the good functioning of the internal market and the free movement of goods while ensuring a high level of protection for health and the environment”. Therefore, it is key for the Applicant to understand how the development of national legal frameworks is influencing the current decision making process in relation to the upcoming legislation.

For the Applicant it is extremely urgent to assess the content of the Requested Documents in order to participate in the Commission’s decision-making process in relation to the legislative proposal, to be able to scrutinize the ongoing decision making process and assess whether all the appropriate options and their consequences are taken into account in the Commission’s development of this upcoming legislation, and to inform the wider public accordingly so that they can also make their voices heard.’

Please note that the Aarhus Regulation sets out the basic terms and conditions for the exercise of the right of public access to environmental information (Article 1). It expressly provides that Regulation (EC) No 1049/2001 shall apply to any request by an applicant for access to environmental information held by the EU institutions and bodies (Article 3). Therefore, it does not establish a separate system of public access to documents that would derogate from the general system put in place by Regulation (EC) No 1049/2001, but merely provides for specific rules, which supplement Regulation (EC) No 1049/2001 in cases where certain specific types of information are concerned. The provisions regarding the application of exceptions to the requests for access to environmental information are governed by Article 6 of the Aarhus Regulation. As Regulation (EC) No 1049/2001 and the Aarhus Regulation belong to the same hierarchical level in the European Union legislative order, no provision expressly gives one regulation priority over the other. In such cases, as confirmed on many occasions by the case-law of the EU Courts, both pieces of legislation should be applied in the way ensuring conformity with each other.

Your request has been assessed on the basis of both Regulation (EC) No 1049/2001 and the Aarhus Regulation. Taking into account the results of this assessment, partial access has been granted to the documents. However, due to the reasons explained above, no further access to the redacted parts is possible at this stage of the decision-making process.

Concerning the other interests outlined in your confirmatory application, 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 process. The reason is that those principles are effectively

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16 In this regard, see 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 56.

implemented by the provisions of Regulation (EC) No 1049/2001 as a whole. In its judgment in the Strack case\(^\text{18}\), 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-disclosure\(^\text{19}\).

General references to the protection of human health are also not sufficient to demonstrate the existence of an overriding public interest\(^\text{20}\), nor is the citizens’ right to be informed about the compatibility of national law with EU law or to participate in decision-making\(^\text{21}\). The same reasoning can be applied by analogy to your argument that disclosure of the documents would be key for your understanding if the development of national legal frameworks is influencing the current decision-making process in relation to the upcoming legislation.

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 question\(^\text{22}\).

The Secretariat-General has moreover not been able to identify any public interest capable of overriding the public and private interests protected by Article 4(2) first indent and Article 4(3) first subparagraph of Regulation (EC) No 1049/2001.

The fact that other documents regarding the same subject matter have already been made publicly available\(^\text{23}\) (for instance, in application of the Better Regulation rules and guidelines), only reinforces this conclusion.

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.

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\(^{23}\) See [https://ec.europa.eu/environment/chemicals/reach/reach_revision_chemical_strategy_en.htm](https://ec.europa.eu/environment/chemicals/reach/reach_revision_chemical_strategy_en.htm).
However, for the reasons explained above, no further 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