EUROPEAN COMMISSION

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Ms Vicky Cann
Corporate Europe Observatory
Rue d’Edimbourg 26
1050 Brussels

DECISION OF THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 4 OF THE IMPLEMENTING RULES TO REGULATION (EC) NO 1049/2001

Subject: Your confirmatory application for access to documents under Regulation (EC) No 1049/2001 – 2022/6860

Dear Ms Cann,

I am writing in reference to your confirmatory application registered on 25 November 2022, 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 25 November 2022, handled by the Regulatory Scrutiny Board, you requested access to ‘any impact assessments on the Reach revision submitted to the Regulatory Scrutiny Board (RSB); all RSB opinions on these impact assessments’.

The European Commission identified the following documents 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’), which contains the following annex:
  - Annexes to the draft impact assessment (hereafter ‘document 1.1’);

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The opinion of the Regulatory Scrutiny Board on the impact assessment, reference Ares(2022)7982198 (hereafter ‘document 2’).

In its initial reply of 12 January 2023, the Regulatory Scrutiny Board in the Secretariat-General 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 I will address 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.

Following this review, I can inform you that I have to confirm the initial decision of Regulatory Scrutiny Board to refuse further access, based on the exceptions of the first subparagraph of Article 4(3) (protection of the decision-making process) and of the first indent of Article 4(2) (protection of commercial interests) 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 ‘Case C-57/16 P1 already ruled 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 which the Commission is obliged to make directly accessible to the public pursuant to Article 12(2) of Regulation No 1049/2001 and that access should not be denied on request. Denying full access to the requested documents stands in clear conflict with this judgment, to which I specifically referred the RSB in my request. The Decision makes no reference to why this jurisprudence is not being followed. In case C-57/16 P the Court of Justice found that draft and final impact assessment documents and RSB reports represent legislative documents.’

Please note that this judgement in the case ClientEarth does not procure a right of direct and unconditional access, but indicates that an individual assessment of the request for access 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 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 concerned³.

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) TFEU does not exclude legislative documents from its scope⁴.

The redacted passages of the Impact Assessment contain information about all policy options, their possible impacts, a comparison of the options, details on a preferred option and the methodology for evaluating impacts. The redactions in the annexes regard 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 Impact Assessment, the conclusion as well as the detailed comments on the Impact Assessment.

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 Sustainability⁵. 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 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 studies, which have been finalised and which feed into the draft impact assessment, are already public⁶.

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⁵ 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.

⁶ Finalised and published studies:
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, the draft Impact Assessment is still being revised throughout 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, 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.

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 to 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 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 of the draft Impact Assessment, its annexes or the RSB opinion 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.

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 may 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 press⁷. Therefore, the risk is very serious and real. As Commission services are still working on the file, they must be free to explore all possible options without constraint in preparation of a 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 the 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’⁸.

Moreover, in your confirmatory request, you consider that the requested documents ‘also contain environmental information within the meaning of Article 2(1)(d) of Regulation 1367/2006’, without explaining further on the basis of which elements you base this assertion.

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,

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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 by the case-law of the Court of Justice, both pieces of legislation should be applied in the way ensuring conformity with each other.

Pursuant to this Article 2(1)(d) “environmental information” means any information in written, visual, aural, electronic or any other material form on: […] (iii) measures (including administrative measures), such as policies, legislation, plans, programmes, environmental agreements, and activities affecting or likely to affect the elements and factors referred to in points (i) and (ii) as well as measures or activities designed to protect those elements; […]”.

Article 6(1) of the Aarhus Regulation provides as follows: ‘[a]s regards Article 4(2), first and third indents, of Regulation (EC) No. 1049/2001, with the exception of investigations, in particular those concerning possible infringements of Community law, an overriding public interest in disclosure shall be deemed to exist where the information requested relates to emission into the environment. As regards the other exceptions set out in Article 4 of Regulation (EC) No. 1049/2001, the grounds for refusal shall be interpreted in a restrictive way, taking into account the public interest served by disclosure and whether the information requested relates to emissions into the environment.’

According to the case-law of the Union Courts, the concept of information relating to emissions into the environment ‘[…] must be understood to include, inter alia, data that will allow the public to know what is actually released into the environment or what, it may be foreseen, will be released into the environment under normal or realistic conditions of use of the product or substance in question, namely those under which the authorisation to place that product or substance on the market was granted and which prevail in the area where that product or substance is intended to be used. Consequently, that concept must be interpreted as covering, inter alia, information concerning the nature, composition, quantity, date and place of the actual or foreseeable emissions, under such conditions, from that product or substance’.

The Court further held that that concept ‘may not, in any event, include information containing any kind of link, even direct, to emissions into the environment’, nor

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9 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.


11 Ibid, paragraph 58.
hypothetical emissions\textsuperscript{12}. If that concept were interpreted as covering such information, it would largely exhaust the concept of ‘environmental information’ within the meaning of the Aarhus Regulation, depriving the institution of any possibility to refuse the disclosure of environmental information\textsuperscript{13}. In its Judgment in Case T-498/14, the General Court ruled that in order to qualify as an environmental information on emissions, the information must contain data that enable understanding to what extent and for which period of time the released substances would contribute to increasing the percentage of emissions risks in the environment\textsuperscript{14}. In the same case, the General Court concluded that, as such, evaluations and proposals do not enable the public to appreciate what is effectively released into the environment\textsuperscript{15}.

The information in the requested documents does not qualify as such as ‘information relating to emissions into the environment’ within the meaning of Article 2(1)(d) or Article 6(1) of the Aarhus Regulation.

The parts of the impact assessment (in particular the section related to the problem definition and the baseline) and its annexes, including information on the present state of the environment and estimations of the potential emissions of certain chemicals to the environment in case of the no change scenario, were disclosed. However, the redacted parts of the impact assessment refer to preliminary estimates and projections of the effectiveness (e.g. the emission-reduction capacity) of the different options to address the identified problem. These estimates are still being revised and refined and cannot be considered as environmental information as they do not reflect information about actual or foreseeable emissions within the meaning of the case-law of the Courts, as specified above.

The requested information does therefore not constitute environmental information or information on the release into the environment of products or substances to the extent that that release is actual or foreseeable under normal or realistic conditions of use of the product or substance, as clarified by the Court in the paragraphs above. They also do not constitute information enabling the public to check whether the assessment of actual or foreseeable emissions is correct, as well as the data relating to the medium or long-term effects of those emissions on the environment.

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, 1.1 and 2 would bring a serious harm to the decision-making process concerned.


\textsuperscript{13} \textit{Stichting Greenpeace Nederland and Pesticide Action Network Europe v European Commission}, T-545/11 RENV, paragraph 58.


\textsuperscript{15} \textit{Ibid}, paragraph 112.
In light of the above, the Secretariat-General concludes that the parts concerned of documents 1, 1.1 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.

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’

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 [...]’

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’

As explained in the section above, both the draft Impact Assessment and its Annexes 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

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of chemicals legislations on REACH, CLP, PIC and POPs\textsuperscript{19}, and more specifically Article II.13.1 thereof, concerning the ownership of the 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 / 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 Impact assessment and its annexes 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 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’\textsuperscript{20}.


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 1 and 1.1 pertaining to non-finalised studies must be refused on that basis.

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(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 ‘[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 an unredacted part of the disclosed impact assessment says, humans and the environment are currently “not sufficiently protected” from exposure to harmful substances, and some categories of workers “do not benefit from the same level of protection … despite being more exposed”. There is a real urgency to address the flaws in the existing REACH regulation. […] It is extremely urgent to assess the full 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 scrutinise 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.’

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.

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.\(^{21}\) The reason is that those principles are effectively implemented by the provisions of Regulation (EC) No 1049/2001 as a

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whole. In its judgment in the Strack case\textsuperscript{22}, 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\textsuperscript{23}.

General references to the protection of human health are also insufficient to demonstrate the existence of an overriding public interest\textsuperscript{24}, nor is the citizens' right to be informed about the compatibility of national law with EU law or to participate in decision-making\textsuperscript{25}.

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\textsuperscript{26}.

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.

The fact that other documents regarding the same subject matter have already been made publicly available\textsuperscript{27} (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.

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

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\textsuperscript{26} 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.

\textsuperscript{27} See https://ec.europa.eu/environment/chemicals/reach/reach_revision_chemical_strategy_en.htm.
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