

LEGAL EXPLANATORY NOTE: REQUEST TO ECHA BY A THIRD PARTY FOR ACCESS TO REGISTRATION DOSSIER

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Introduction

According to article 118.1 of REACH, interested parties can request ECHA access to documents. Indeed, the horizontal EU Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents is also applicable to documents held by the Agency. The directly applicable Regulation has been implemented to the Agency's work by the Decision on public access to documents, implementing Regulation 1049/2001 which dates from 2008.

The general principle of Regulation (EC) No 1049/2001 provides for **public access to documents** held by European Institutions. If someone submits a request to ECHA to access any document, e.g. to a registration dossier, ECHA will start by assessing whether an exception to the general principle applies (as set out in Article 4 Regulation 1049/2001). If it considers that one of the exceptions applies, it will refuse access. If it considers on the contrary that it is clear that there is no such exception or that the document has already been disclosed, it will grant access. In the remaining cases it will contact the concerned registrant to consult on whether an exception could be applicable. Registrants may start receiving this kind of requests from ECHA at any time and indeed some have already been received.

Since according to the Regulation and the Decision, ECHA has only 15 working days to answer to the request of the interested party, ECHA is only able to give a **very short time for the registrant concerned to react** and prepare the submission of confidentiality justifications (5 working days), which may represent extra workload for registrants.

This process should **not be confused with the process of confidentiality claims** related to the general publication of the information on the ECHA website (119.2 REACH), since their scope, rules and the rationale on which the two processes are based are different. Therefore, the fact that certain information is not automatically disseminated on ECHA's website (e.g. CSR) or the fact that a registrant has claimed certain information confidential at the time of submitting the dossier, does not preclude the possibility that access to said document may be granted to a particular requestor in the framework of the Access to Documents Regulation.

The process based on the request of access to documents may cover any kind of document held by ECHA (e.g. decisions, opinion from a Member State) but the present paper is focused on requests for access to a registration dossier.

I. Context: the regulatory framework set by Article 118 REACH

According to REACH Recital 117, EU-citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions



about their use of chemicals. Free and easy access to basic data held at the Agency's database is recognized as a transparent means to achieve this goal.

Article 118 REACH refers to the rules of the Access to Documents Regulation (EC regulation 1049/2001). These rules promote the widest possible access to documents but foresee as an **exception** that an institution shall not disclose information that 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 addition, the possibility of consultation of the data submitter by the EU institution before making a document public is foreseen.

It is important to note that Article 118(2) already lists information whose disclosure is normally deemed to undermine the commercial interests of the data submitter and will normally not be made available to the public unless an emergency situation occurs with respect to human health, safety or the environment.

In the context of the Access to Documents Regulation, in accordance with existing case law, institutions enjoy a certain margin of discretion when deciding whether or not certain information should qualify as confidential (definition of the type of information that is potentially confidential, evaluation of validity of any justifications given, balancing of particular interests with general interests). In particular, compared to assessment of confidentiality claims regarding dissemination on ECHA website (art. 119(2)), ECHA enjoys a larger margin of discretion: **convincing justifications should be elaborated**.

II. Legal basis

-Articles 77 (2) (e) and 118 REACH.

-[Regulation 1049/2001](#) on access to documents (horizontal regulation applicable to EU institutions which is in the process of being amended with the aim to grant broader access).

-MB/12/2008 [ECHA Decision](#) on the implementation of Regulation (EC) n° 1049/2001 of the EP and the Council regarding public access to documents¹.

III. Process

-Any natural or legal person within the EU and elsewhere can request access to a document held by ECHA. The applicant does not need to justify the request. The request should be submitted in writing (website, mail, e-mail or fax) to ECHA. See in particular the form available from ECHA website: http://echa.europa.eu/about/access_docs_en.asp

-ECHA has 15 working days to answer to such request (+ 15 additional working days under exceptional circumstances).

-In case the document requested is not an ECHA document but a "third party" document (in this case, a registration dossier from a REACH registrant), ECHA may consult the 3rd party (the registrant) to assess whether an exception under Art. 4 of Regulation 1049/2001 is applicable that justifies non-disclosure, such as for example the protection of the commercial interests, including intellectual property (see also Introduction, 2nd paragraph).

¹ [Regulation \(EC\) No. 1367/2006](#), which transposes the legal requirements of the Aarhus Convention on access to environmentally relevant information, also applies to ECHA although not specifically mentioned in Article 118. It is insofar of importance as it states that the grounds for refusal have to be interpreted in a restrictive way.

However, no such consultation with the registrant is needed if it is clear to ECHA that the document should or should not be disclosed. In the consultation, ECHA will ask which exact parts of the document should not be disclosed and a justification will be requested in order for ECHA to make an informed decision.

-The registrant may receive the communication from ECHA in its REACH-IT mail box and/or in the contact's company e-mail mailbox.

-The registrant is given at least 5 working days to reply.

-The identity of the applicant will remain unknown to the registrant.

-Based on the reply from the registrant (if any), ECHA takes the decision and informs the applicant thereof. In case where the Agency decides to disclose the document against the position of the registrant, according to Article 5(6) of ECHA's implementing rules, it informs the registrant of its intention to disclose the document giving the registrant a 10 working day period to seek legal remedies.

-Remedies for the registrant:

1. Action before the Court of Justice of the European Union (General Court, formerly named the Court of First Instance). It should be noted that an action for annulment has no suspensive effect and the only way to stop the disclosure is to lodge an application for interim measures.

2. Complaint to the European Ombudsman about maladministration (with no suspensive effect).

The ECHA Board of Appeal is not empowered to rule in this field.

IV. Reply from registrant to ECHA on the disclosure of information from the dossier

Any reply to ECHA is case by case, but here is a **suggestion of a reply** where you will find several paragraphs that could be combined as appropriate:



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to ECHA_ access to d

In this example, due to the future dissemination of the main part of the technical dossier on the ECHA website, its disclosure is authorised. However, the non-disclosure of the CSR is requested to ECHA. The reasoning is built on the explanation of presence of Confidential Business Information in the CSR and on the commercial added value of CSR, due to the work subject to compensation in the SIEF.

This paper has been developed by the Cefic Legal Aspects of REACH Issue Team.

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