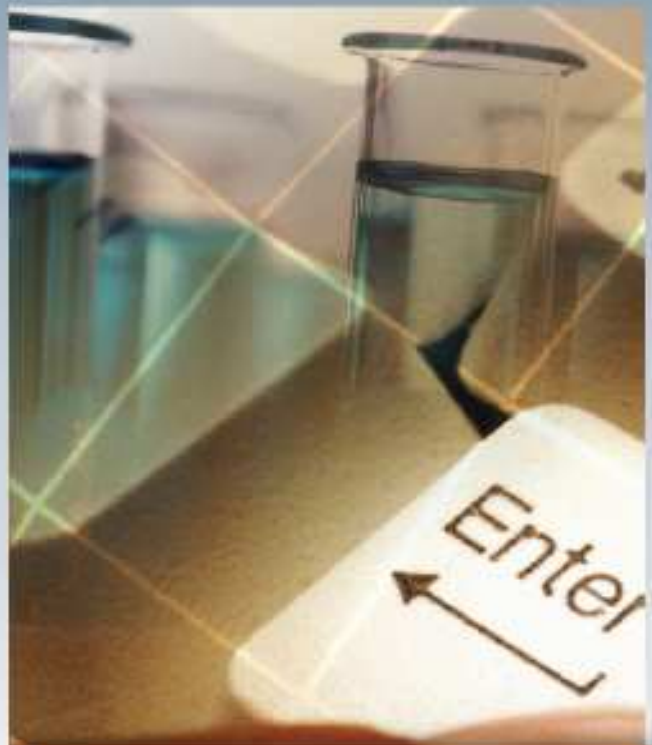


Questions and answers on Data sharing and related disputes



For the latest news and the most up-to-date information, please consult the ECHA website.

LEGAL NOTICE

This document contains questions and answers on data sharing rights and obligations under Regulation (EC) No 1907/2006 (REACH Regulation).

However, users are reminded that the text of the REACH Regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC) is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

Questions and answers on data sharing and related disputes

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Key messages

- 1) REACH requires registrants and/or potential registrants to make every effort to ensure that the cost of sharing the information required for registration are determined in a fair, transparent and non-discriminatory way.
- 2) All parties must fulfil their data sharing obligations in a timely manner. In the case of phase-in substances subject to the first registration deadline, SIEF participants are encouraged to allow a reasonable time for the negotiations before the registration deadline. If appropriate, this may imply that they initiate their efforts to ensure the sharing of the information even before the actual submission of the joint dossier.
- 3) In accordance with REACH, ECHA has set up procedures to assist in the resolution of data sharing disputes. Data sharing dispute procedures must be initiated as a last resort, i.e. only after all the possible efforts and arguments have been exhausted and the negotiations have eventually failed.
- 4) Any potential registrant involved in a data sharing dispute must always obtain a decision from ECHA **before** submitting the registration dossier, granting the permission to proceed with registration. Dossiers submitted while a data sharing procedure is still pending will not comply with the data requirements.
- 5) In so far as data sharing activities take place outside REACH-IT, companies are advised to carefully record any communication with another party, as this may be requested by ECHA in the context of a data sharing claim or by national competent authorities for enforcement purposes.
- 6) In case of dispute, ECHA's permission to proceed with registration will be based on an assessment of the parties' respective efforts to reach an agreement on the sharing of the data and its costs in a fair, transparent and non-discriminatory way.
- 7) A potential registrant initiating a data sharing dispute procedure with ECHA must demonstrate the efforts made by all the parties to reach an agreement and must provide appropriate documentary evidence.
- 8) Pending the processing of a data sharing dispute, ECHA encourages all parties to continue making every effort to reach an agreement.
- 9) A potential registrant initiating a data sharing dispute procedure can only expect a favourable decision from ECHA if it results from the information available that he has made every effort to reach an agreement before contacting ECHA.
- 10) Beside data sharing obligations, the registrants of the same substance, whether phase-in or non-phase-in, shall also fulfill their obligation to submit jointly data in accordance with article 11 of the REACH Regulation.

1. Background

1.1 What is data sharing about?

Data sharing is one of the core principles in Regulation (EC) no 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). By submitting dossiers jointly and sharing information on substances, companies increase the efficiency of the registration system, reduce costs and avoid unnecessary testing on vertebrate animals.

Potential registrants have an obligation to request that studies involving vertebrate animals are shared, whereas they have the option to request the sharing of data not involving testing on vertebrate animals. In any case, if a study is requested, its owner is obliged to share it, whether or not the study involves testing on vertebrate animals.

This principle, which applies to both phase-in and non- phase-in substances, results in the fact that studies involving testing on vertebrate animals can **only** be conducted as a last resort, if the data cannot be obtained from a registrant or potential registrant subject to a data sharing obligation. The test may sometimes be actually conducted later, if REACH stipulates that a testing proposal shall first be submitted to ECHA.

The REACH Regulation sets out the rules implementing the data-sharing principle in Article 27, in relation to non phase-in substances, and in Article 30, in relation to phase-in substances. In addition, the Regulation contains provisions which can be followed in the case of data sharing disputes between registrants.

The REACH Regulation also allows the owner of data to be able to claim compensation for a period of 12 years from those registrants who benefit from that data. This “12 year-rule” applies to any data subject to a study summary or robust study summary, which has been submitted in the framework of a registration, either to ECHA or to national competent authorities (under the dangerous Substance Directive 67/548/EC). This rule applies to both phase-in and non phase-in substances.

Beside the data sharing obligation, the registrants and potential registrants of the same substance will also have to ensure that the joint submission obligation set out in article 11 of the REACH Regulation is fulfilled.

1.2. What is the role of ECHA in data sharing or related disputes?

ECHA aim at guaranteeing that registrants and/or potential registrants make every effort to ensure that the costs of sharing information required for registration are determined in a fair, transparent and non-discriminatory way. Hence ECHA will not assess whether the claim (costs or conditions under which sharing is proposed) is justified.

As an example, sharing would be considered as being:

- not fair, if the data owner requests the full cost of the study he paid where there are several other registrants;
- not transparent, if the data owner requests the payment of a generic fee for the data contained in the joint registration dossier, without providing detailed information on the costs.
- discriminatory, if the costs of the same study would be different for EU manufacturers and importers or only representatives.

The ECHA data sharing dispute procedure should be initiated as the last resort, i.e. after all the possible arguments have been exhausted and the negotiations have eventually failed.

2. Data Sharing in relation to non phase-in substances and phase-in substances which have not been pre-registered

2.1. Why do I need to make an inquiry?

Any potential registrant of a non-phase-in substance or of a phase-in substance which has not been pre-registered has a duty to inquire from ECHA, whether a registration has already been made for the same substance (Article 26 of the REACH Regulation). A registrant willing to update its dossier shall also previously submit an inquiry (Article 12(2) of the REACH Regulation). This legal obligation ensures that data are shared by the relevant parties and that animal testing is not unnecessarily repeated.

The inquiry and its outcome will depend on whether the data concerning a prior registration, if any, has been submitted more or less than 12 years prior to the date of the inquiry.

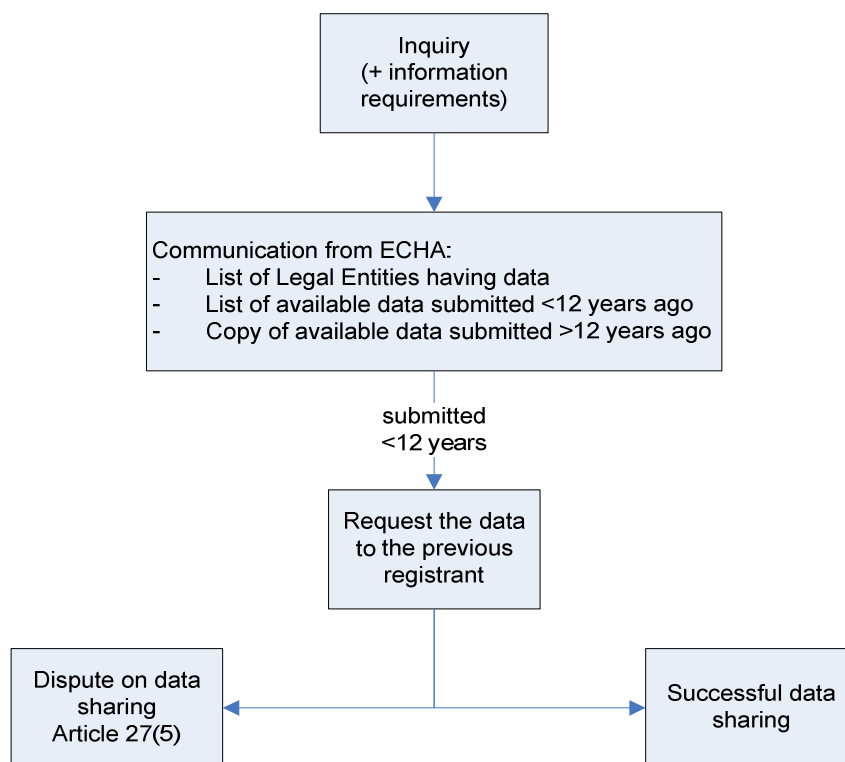


Figure 1: Data sharing process following an inquiry

Further details on the inquiry procedure can be found on the ECHA website at: http://www.echa.europa.eu/reachit/inquiry_en.asp

2.2. What happens after I submitted my inquiry, in relation to data sharing?

Following an inquiry the potential registrant will receive a communication from ECHA on whether the substance has previously been registered (or notified under Directive 67/548/EC on classification, labelling and packaging of dangerous substances). In that case, ECHA will inform the potential registrant of the name(s) and address(es) of the previous registrant(s) and, if appropriate, other inquirers. This communication will enable the potential registrant to request the sharing of existing data.

If the potential registrant did not, at the time of the inquiry, list the endpoints he requires in order to register, ECHA will only inform them about the identity of previous registrants.

If the potential registrant indicated to ECHA in his inquiry the information requirements applicable to him, ECHA will also provide the list of available (robust) study summaries already submitted.

- Studies were submitted at least 12 years previously (see question 2.3. below)

ECHA will indicate in its reply, if (robust) study summaries have been submitted at least 12 years previous to the date of the inquiry. In that case, the potential registrant can ask ECHA to provide a copy of the relevant studies, which can be used for the purpose of registration by the potential registrant (Article 26 of the REACH Regulation).

- Studies were submitted less than 12 years previously (see question 2.4. below)

The potential registrant has to request directly from the previous registrant(s) the (robust) study summaries he requires in order to register. A request **must** be made for any studies involving vertebrate animals. However, a request **may** be made for studies not involving vertebrate animals.

2.3. How to use data submitted at least 12 years previously for my registration?

The situation

The substance has been registered and the relevant studies were submitted more than 12 years before the inquiry is made.

Rights and obligations

According to article 25(3) of the REACH Regulation, where the data has been submitted for a registration at least 12 years prior to the date of an inquiry, these data can be used for the purposes of registration in the EU by another manufacturer or importer without compensation of the original data submitter (see section 1.1).

The process

Study summaries or robust study summaries submitted for the same substance at least 12 years previously are provided by ECHA following the inquiry process as set out in Article 26. The potential registrant submitting an inquiry including the list of data requirements will, as of July 2010, automatically receive from ECHA this data.

Data obtained from ECHA can only be used in the context of a registration under REACH, and not for any other purposes.

NB: for inquiries submitted prior to July 2010, the potential registrant can ask ECHA (via the ECHA Helpdesk providing the inquiry communication number and EC number) to provide them with the copies of the relevant (robust) study summaries as indicated in the reply from ECHA to the inquiry.

A potential registrant may also inquire about a substance which is an analogue of the substance that he intends to register, with a view to using the data on the analogue substance for read-across or to form a chemical category, in order to fill a data gap for the registration of his substance. In that case, the potential registrant needs to state the EC number of the substance of interest. Although ECHA may provide access to data on analogue substances, it remains the exclusive responsibility of the potential registrant to decide whether the read-across principle is applicable to their substance. Should the potential registrant use a read-across argument in their registration dossier, they are also required to provide a scientific justification. This justification may be assessed later at the stage of compliance check or substance evaluation.

It is the responsibility of the potential registrant to assess and acknowledge the quality, relevance and reliability of the data that they may include in the registration dossier. The fact that ECHA has passed on information already submitted does not provide any guarantee on its quality, relevance and reliability in relation to the registration of the substance, especially in providing appropriate risk management measures for the safe use of the substance or in order to draw the appropriate conclusions in the chemical safety assessment.

- If the potential registrant considers that the (robust) study summaries provided by ECHA do not meet the quality standards required under REACH, they may wish to draft new (robust) study summaries relating to the same study. It might in that case

be necessary to contact the previous registrant in order to obtain the original study report.

- If the potential registrant considers that the studies subject to (robust) study summaries provided by ECHA do not meet the quality, relevance and reliability conditions, they may conclude that the endpoint is not sufficiently characterised.

2.4. How to obtain from a previous registrant data submitted less than 12 years previously?

The situation

The substance has been registered but the relevant studies were submitted less than 12 years before the inquiry. ECHA informs the potential registrant of the names and addresses of the previous registrant(s) but cannot provide a copy of the (robust) study summaries.

Rights and obligations

For the purposes of data sharing, the potential registrant will need to contact the previous registrant(s) (and/or the other inquirer(s)) identified by ECHA.

A request for sharing information **must** be made for any studies involving vertebrate animals. However, a potential registrant has the option to request data from the previous registrant(s) if that data does not involve testing on vertebrate animals.

The previous registrant and the potential registrant shall make every effort to reach an agreement on the sharing of the data requested and its costs. The obligation to make every effort applies to any information requested, whether they concern vertebrate or non-vertebrate animal studies.

The process

Once a data sharing request for studies submitted less than 12 years ago has been made, both the previous and potential registrants must make every effort:

- to reach an agreement on the sharing of the information requested by the potential registrant;
- to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way.

2.5. What can I do if I cannot agree on the sharing of the data or the costs with the previous registrant?

The situation

In case of failure of the previous registrant and the potential registrant to reach an agreement on sharing the data or the costs, the potential registrant can ask ECHA to be granted the permission to refer to the data.

Rights and obligations

According to Article 27(5), if the previous registrant and the potential registrant fail to reach an agreement to share data or their costs, the potential registrant shall inform ECHA of this failure at the earliest one month after the original receipt from ECHA of the contact details of the previous registrant. The potential registrant shall also notify the previous registrant that they have informed ECHA.

The potential registrant will receive from ECHA the permission to refer to the data, if ECHA considers that the request is founded, i.e. if it is demonstrated by documentary evidence that the previous registrant has not met his obligation to make every effort to share the data and its costs in a fair, transparent and non discriminatory way, although the potential registrant has made such efforts.

The previous registrant shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts.

The process

To initiate the process, information on the dispute is to be provided to ECHA using a webform, available on the ECHA website at: <https://comments.echa.europa.eu/comments/article275.aspx>,

and including any documentary evidence demonstrating that:

- they have made every effort to share the information and to agree on the sharing of the costs in a fair, transparent and non-discriminatory way;
- they have notified the previous registrant(s) that ECHA will be informed of the failure to reach an agreement.

Subsequently, ECHA will request the previous registrant(s) to provide evidence of the arguments and justifications they used during the negotiations with the potential registrant, if any. This information is to be provided within a period of 10 working days.

ECHA will then perform an assessment of whether a party has breached its obligation to make every effort on the basis of the documentation provided by both parties. Especially in the case of no response to requests for data sharing ECHA will consider the efforts on the basis of different criteria, including the number of attempts to contact the other parties and the quality of these attempts (e.g. registered letter, acknowledgement of receipt, ...).

Where ECHA decides to grant permission to the potential registrant to refer to the information, it will first ask the potential registrant to provide a proof of payment of a **share of the costs** incurred by the previous registrant for generating the data. The proof of payment

may take any appropriate form, including a bank statement or a postal order (note that postal order may be limited to a certain amount).

Upon receipt of this proof of payment, ECHA will provide a copy of the (robust) study summaries on the relevant endpoint(s) and grant the potential registrant a permission to refer to them.

More specifically, the procedure within ECHA will develop as follows:

- ECHA will provide a decision whether or not to grant a permission to refer within one month after having received complete information from both parties;
- upon conclusion that a permission to refer should be granted, ECHA will request the proof of payment of a share of the costs. This request will suspend the 1-month period;
- when ECHA receives the proof of payment, it will start again the countdown of the procedure. ECHA will then send the final decision before the expiry of the 1-month period, together with a copy of the (robust) study summaries.

The previous registrant shall have a claim against the potential registrant before a national court to recover the costs if they consider that the share of the costs paid by the potential registrant is not appropriate.

ECHA encourages all parties to continue to make every effort to reach an agreement even after notifying a dispute to ECHA. Should an agreement be reached before ECHA takes its decision, the potential registrant should inform ECHA as soon as possible, and the procedure will be cancelled.

The potential registrant or the previous registrant(s) may lodge an appeal against the decision of ECHA to grant permission or not to grant permission to refer to the data. Further details on the appeal procedure can be found at: http://echa.europa.eu/appeals/app_procedure_en.asp.

NB: The potential registrant must obtain a decision from ECHA granting the permission to refer to the data and confirming that they have met their obligations **BEFORE** submitting the registration.

2.6. What can I do to extend the waiting period of the new registrant to benefit from the provisions of article 27(8)?

The situation

A previous registrant and a potential registrant have agreed on the sharing of information submitted less than 12 years previously or, following a data sharing dispute, ECHA grants the potential registrant a permission to refer to the data.

Rights and obligations

Ahead of the submission of their registration dossier by the potential registrant, the previous registrant may, pursuant to Article 27(8), ask ECHA to extend the registration waiting period by an additional four months.

Accordingly the potential registrant, upon receipt of confirmation of his successful registration, will have to wait for an extra period of 4 months before being entitled to manufacture or import the substance.

The process

The previous registrant can make the request to ECHA using the following email address:

datasharing-disputes@echa.europa.eu.

The previous registrant will need to provide the Communication number (such as INQ-C-0000000000-00-00) received from ECHA following the inquiry of the potential registrant.

As a result, ECHA will inform, via REACH-IT, the potential registrant that the previous registrant requested to extend the registration waiting period by an additional four months. ECHA may check the effective data sharing with the potential registrant.

Upon receipt of their registration number, the potential registrant will have to wait until the expiry of the additional waiting period before being entitled to manufacture or import the substance on the European market.

3. Data Sharing within SIEF

3.1. What are the duties related to data sharing within a SIEF?

The formation of a Substance Information Exchange Forum (SIEF) enables potential registrants and data holders to share information on the same phase-in substance in order to prevent duplication of testing, especially testing on vertebrate animals. To prepare the common parts of the joint submission, the members of a SIEF need to gather and assess the availability of data on the intrinsic properties of the substance, and subsequently ensure that the cost of this data is shared in a fair, transparent and non-discriminatory way. ECHA does not have a role in the organisation and operation of SIEFs.

The REACH Regulation indicates that, before further testing involving vertebrate animals is carried out, SIEF members shall ensure that a relevant study is not already available by requesting it within their SIEF. SIEF members may also choose to request whether any relevant non-vertebrate animal study is available. If a requested study is available to one member of that SIEF, he is obliged to make that study available to the other potential registrants, subject to sharing of the cost.

NB: If members of a SIEF become aware that another SIEF is dealing with the same substance, it is their responsibility to make every effort to merge the two SIEFs and submit one single joint submission. They should co-operate by sharing data and costs as well as justifying the decision to merge.

Any SIEF member receiving a request for data (related to both vertebrate and non-vertebrate testing) shall provide a proof of the cost within one month.

It is the responsibility of both the data owner and the other member(s) of the SIEF to make every effort to reach an agreement on the sharing of the costs, which must be determined in a fair, transparent and non-discriminatory way.

NB: Article 30 of the REACH Regulation sets out the rules applicable to data sharing disputes within a SIEF. It covers disputes resulting from disagreement on who shall conduct a new test and dispute resulting from disagreement on the principle and/or the conditions of sharing existing vertebrate studies.

3.2. What can I do if there is a data gap identified within my SIEF and no one is willing to conduct the new test?

The situation

In case a study (whether or not involving vertebrate animals) is needed for registration (i.e. from Annexes VII and VIII) and is not available within the SIEF, a new test will need to be conducted in order to complete the dossier. However, the SIEF members cannot agree on who will conduct the missing study, despite all their efforts to reach an agreement.

Rights and obligations

In accordance with Article 30(2) of the REACH Regulation where SIEF participants cannot agree, ECHA should specify which registrant shall perform the test. After the test is performed, all members of the SIEF, who require the study, shall contribute to its costs with a share corresponding to the number of participating potential registrants.

The process

Where no agreement on who shall conduct the new test can be reached among SIEF members, one of the SIEF members can inform ECHA by using a webform available on the ECHA website at: <https://comments.echa.europa.eu/comments/article302.aspx>,

and by providing the information listed below (the template is provided with the webform):

- The (company) names of the SIEF members that have tried to reach an agreement;
- The (company) names of the SIEF members supporting the claim that a test is needed;
- The (company) names of the SIEF members volunteering to perform the test.

Based on the information provided, ECHA will select the registrant who will perform the study on the basis of objective criteria, including active participation in the preparation of the dossier and the deadline applicable to the respective registration of the SIEF members.

Once they performed the study, the registrant shall submit it to ECHA before the prescribed deadline. In addition, this registrant shall provide the full study report to those SIEF members who require the test and paid a share corresponding to the number of participating registrants, within 2 weeks of the payment.

NB: This procedure only applies in case of disagreement on who shall perform a necessary testing and not in case of disagreement on the need to conduct the given study. Therefore submitting the webform cannot result in imposing a specific new test on other SIEF members disagreeing on the content of the joint submission dossier. ECHA will not assess the reason for the disagreement or whether the testing is required or justified.

Furthermore, ECHA encourages parties to continue to make every effort to reach an agreement on who will perform the study before it designates a SIEF participant. Should an agreement be reached before that decision, the potential registrant who made the claim on the webform shall inform ECHA as soon as possible.

NB: The potential registrant(s) must obtain a decision from ECHA designating a SIEF member **BEFORE** submitting the registration.

3.3. What can I do if, while preparing the joint registration, the owner of an existing vertebrate study within the SIEF is not willing to share his data or refuses to provide proof of its costs?

The situation

A SIEF member has requested a vertebrate animal study to be shared, during the preparation of the joint registration to be submitted. Furthermore, within one month of receiving the request, the owner of the study refuses to provide the proof of the costs of that study or the study itself.

Rights and obligations

Pursuant to Article 30(3) of the REACH Regulation the owner of the vertebrate animal study shall not be able to proceed with registration until he provides the information to the other SIEF participant(s).

On the other hand, the other participant(s) shall proceed with registration without fulfilling the relevant information requirement, provided that they have received the permission from ECHA to do so.

This procedure only applies to disputes regarding studies involving vertebrate animals. In case the data sharing dispute also concerns studies not involving vertebrate animals, Article 30(4) requires the potential registrant(s) to proceed with registration as if no relevant study was available in the SIEF. Consequently the potential registrant(s) will have to perform individually such studies, prior to submitting a complete registration dossier.

The process

In principle, the dispute may affect several SIEF members simultaneously. The SIEF member(s) seeking to access the vertebrate animal data, can contact ECHA using the webform available on the ECHA website at: <https://comments.echa.europa.eu/comments/Article303.aspx>.

The SIEF concerned may possibly be represented by one of them, provided that they can all demonstrate that they have made, individually or collectively, every effort to share the requested data.

Before a claim is made, ECHA recommends that the SIEF members concerned jointly make a final notice to the owner of the study in order to reach an agreement.

The potential registrant(s) will have to specify on the webform the vertebrate animal studies they requested from the data owner. Accordingly, the SIEF member(s) will need to provide ECHA with all the **documentary evidence** demonstrating the efforts that **all parties** have made in order to reach an agreement under fair, transparent and non-discriminatory conditions. This includes not only the arguments of the requesting SIEF member(s), but also the arguments of the owner of the data. The documentary evidence may consist of:

- correspondence requesting the conditions for data sharing;
- correspondence from the owner describing the conditions for the sharing of the data;

- correspondence challenging the conditions imposed by the owner of the data;
- any further justification of, or modification of, the conditions provided by the owner of the data;
- correspondence challenging these justifications that the other participants would consider unfair, non transparent or discriminatory.

An informed and balanced assessment of their dispute requires the potential registrant to provide ECHA with any copies of the letters and other documents sent to, or received from, the data owner.

ECHA will then ask the data owner to also provide, within 10 working days, the documentary evidence relating to the arguments and justifications used by them during the negotiation. Indeed ECHA will assess that all parties met their obligations to make every effort to reach an agreement on the sharing of the data. ECHA also ensures that such requests are handled in a balanced way, taking into account the interests of both the owner of the data and the other SIEF member(s).

The decision to grant permission to proceed without fulfilling the relevant information requirements will be taken following the receipt of all information. In the case of no response to requests, ECHA will consider the efforts of the parties on the basis of different criteria, including the number of attempts to contact the data owner and the quality of these attempts (e.g. registered letter, acknowledgement of receipt, ...). If the data owner does not provide the requested information within the deadline set, ECHA will conduct its assessment and take a decision only on the basis of the available information that was provided by the other SIEF member(s).

Where the data owner has not made every effort to reach an agreement, ECHA will provide the SIEF member(s) with a permission to proceed with registration without fulfilling the relevant information requirement.

NB: The potential registrant(s) must obtain a decision from ECHA granting the permission to proceed **BEFORE** submitting the registration without the study.

The registrant(s) will have to indicate in the registration dossier header the reason for not providing the study and shall refer to the permission granted by ECHA.

The procedure set out in Article 30(3) of the REACH regulation is only a default mechanism in case of absence of agreement on the sharing of a study. It shall therefore be only initiated as a last resort, after all the possible arguments have been exhausted and the negotiations have eventually failed.

The defaulting data owner will not be entitled to manufacture or import the substance after the registration deadline.

In principle the REACH Regulation provides for ECHA to request the test to be repeated. Even if the registrant(s) are allowed to submit the dossier without the study, all the parties shall continue their efforts to reach an agreement on the sharing even after the registration has been submitted.

Both parties can lodge an appeal against the permission granted by ECHA to proceed with registration without the study and preventing the owner of the data from proceeding with registration until he provides the information to the other participants. Further details on the appeal procedure can be found at: http://echa.europa.eu/appeals/app_procedure_en.asp.

Financial penalties

The assessment performed by ECHA in the context of a data sharing dispute, may result in the determination that the owner of a study has breached their obligation to make every effort to reach an agreement on sharing the study. According to article 30(6) of the REACH Regulation, the owner of a study in breach of this obligation may also be subject to financial penalties to be imposed by the enforcement authorities of the Member State where he is established.

Other possible actions

Other remedies may also exist beside Article 30(3), especially in relation to competition law. Accordingly, if the behaviour of the data owner has the object or the effect of preventing, restricting or distorting competition, the competition authorities at European or national level, or the competent national courts may also be approached. For more details on the prohibition of antitrust behaviours, please consult the relevant webpage of the European Commission–Directorate General Competition, on the following link: http://ec.europa.eu/competition/antitrust/overview_en.html

In case of uncertainty, ECHA would recommend to seek legal advice from a lawyer specialised in competition law.

3.4. What can I do if the joint registration was already submitted to ECHA and the existing registrants do not share the submitted data?

The situation

Within the SIEF, a data sharing dispute arises between existing registrants and subsequent potential registrants. For instance, SIEF members with lower tonnage and therefore later submission deadlines will seek to share the content of a registration already submitted by registrants subject to earlier deadlines.

For instance, a dispute may arise in the case where the previous registrants (or their representative, in principle the lead registrant) have not replied to several requests for sharing the data in the joint submission, including by registered mail. A dispute may also arise on the conditions of the sharing. For instance, it would also be the case if the previous registrants (or their representative) have only requested the payment of a generic fee for the data contained in the joint registration dossier, without providing detailed information on the costs.

Rights and obligations

In accordance with the objectives of REACH, the data sharing obligations also apply in the case of studies contained in a registration already submitted. It is the responsibility of all parties (the potential registrant and the previous registrant(s) or their representative) to make every effort to reach an agreement on the sharing of the data and of its costs under fair, transparent and non-discriminatory conditions.

Accordingly, Article 30(3) of the REACH Regulation also addresses disputes on the sharing of existing studies involving vertebrate animals contained in a registration that has already been submitted. However, concerning the aspects of the dispute relating to studies not involving vertebrate animals, Article 30(4) of the REACH Regulation requires the potential registrant(s) to proceed with registration as if no relevant study was available in the SIEF. Consequently the potential registrant(s) will have to perform individually such studies, prior to submitting the registration dossier.

The process

When the joint registration has already been submitted, the dispute may relate to more than one individual study involving vertebrate animals and may concern the total set of data contained in the joint submission.

The potential registrant making every effort to share the data contained in the registration (joint submission) dossier can contact ECHA, using a webform available on the ECHA website at: <https://comments.echa.europa.eu/comments/Article303.aspx>

The potential registrant will have to specify the vertebrate animal studies they requested from the previous registrant(s) (or their representative).

Accordingly, the potential registrant will need to provide ECHA with all the **documentary evidence** demonstrating the efforts that **all parties** have made in order to reach an agreement under fair, transparent and non-discriminatory conditions. This includes not only their requests and their own arguments, but also the arguments of the previous registrant(s), such as:

- correspondence requesting the conditions for sharing the data;
- correspondence from the owner describing the conditions for the sharing of the data;
- correspondence challenging the conditions imposed by the potential registrant (or their representative);
- any further justification of, or modification of, the conditions provided by the potential registrant (or their representative);
- correspondence from the potential registrant challenging these justifications that would be considered unfair, non transparent or discriminatory.

An informed and balanced assessment of the dispute requires the potential registrant(s) to provide ECHA with any copies of the letters and other documents sent to, or received from, the existing registrant(s), or their representative.

ECHA will then ask the previous registrant(s) (or their representative) to provide, within 10 working days, the documentary evidence containing the arguments and justifications used during the negotiations. Indeed in order to decide, ECHA needs to assess that all parties met their obligations to make every effort to reach an agreement on the sharing of the data. ECHA also ensures that such requests are handled in a balanced way, respecting the interests of all parties (the owners of data, the previous registrant(s), the lead registrant and the potential registrant(s)). In the case of no response ECHA will consider the efforts on the basis of different criteria, including the number of attempts to contact the other parties and the quality of these attempts (e.g. registered letter, acknowledgement of receipt, ...).

The decision to grant permission to refer to the relevant vertebrate animal studies will be taken following the receipt of all information from all parties.

If the previous registrant(s) do not provide the requested information within the deadline set, ECHA will conduct its assessment only on the basis of the available information that was provided by the potential registrant.

This procedure only applies to studies involving vertebrate animals and contained in the registration dossier already submitted. Where the previous registrant(s) (or their representative) have not made every effort to reach an agreement on sharing the costs in a fair, transparent and non-discriminatory way, ECHA will provide the potential registrant with a permission to refer to the set of vertebrate animal studies. ECHA will also provide a copy of the relevant (robust) study summaries. The studies concerned are those contained in the joint registration dossier and covered by the negotiations between the potential registrant and the previous registrant(s) (or their representative).

The previous registrant(s) shall have a claim on the subsequent registrant(s) for an equal share of the cost, provided that they make the full study report available to the potential registrant(s). The claim shall be enforceable in the national courts.

NB: The potential registrant must obtain a decision from ECHA granting the permission to refer to the information **BEFORE** submitting their registration.

The potential registrant will have to indicate in the registration dossier header the reason for not providing the study and to refer to the permission granted by ECHA. Consequently, if the potential registrant is not provided by the previous registrant with the information relating to the joint submission (name and security token), the potential registrant will not benefit from the joint submission reduced fee. Indeed, in the case of individual submission, Articles 3(3)

and 4(3) of the REACH Fee Regulation (EC) No 340/2008 prescribe a specific registration fee. However, if the previous registrants are declared in default of sharing the data already submitted, the potential registrant may have the possibility to claim compensation from the previous registrants before a relevant national court for the extra cost of registration.

Other SIEF members involved in disputes in the same SIEF may be willing to make a similar claim. They will need to demonstrate that they have individually or collectively made every effort to reach an agreement with the previous registrant(s) (or their representative). Before a claim is made, ECHA recommends that they jointly make a final notice to the owner of the study to reach an agreement under fair, transparent and non-discriminatory conditions.

Parties can lodge an appeal against the decision of ECHA to grant permission to refer and to proceed with registration. Further details on the appeal procedure can be found at: http://echa.europa.eu/appeals/app_procedure_en.asp

Financial penalties

The assessment performed by ECHA in the context of a data sharing dispute between a potential registrant and other registrant(s), may result in the determination that the previous registrant(s) have breached their obligation to make every effort to reach an agreement on sharing the data. According to Article 30(6), the parties in breach of this obligation may also be subject to financial penalties imposed by the enforcement authorities of the Member State where they are established. These financial penalties would concern the failure to meet their obligation in relation not only to vertebrate animal studies but also to studies not involving testing on vertebrate animals.

Other possible actions

Other remedies may also exist beside Article 30(3), especially in relation to competition law. Accordingly, if the behaviour of the data owner has the object or the effect of preventing, restricting or distorting competition, the competition authorities at European or national level, or the competent national courts may also be approached. For more details on the prohibition of antitrust behaviours, please consult the relevant webpage of the European Commission–Directorate General Competition, on the following link: http://ec.europa.eu/competition/antitrust/overview_en.html.

In case of uncertainty, ECHA would recommend to seek legal advice from a lawyer specialised in competition law.

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