

[REDACTED]
30 May 2023

The Claimant

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Copy to:
The Other Party

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Sent via REACH-IT

Decision number: [REDACTED]
Dispute reference number: [REDACTED]
Name of the substance (the 'Substance'): [REDACTED]
EC number of the Substance: [REDACTED]

DECISION ON A DISPUTE RELATED TO THE SHARING OF DATA

A. Decision

Based on Article 27(6) of Regulation (EC) No 1907/2006 ('REACH Regulation')¹ and Article 5 of the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data sharing in accordance with REACH ('Implementing Regulation 2016/9')²,

ECHA grants the Claimant permission to refer to information requested from the Other Party for the purpose of a registration under the REACH Regulation. However, this decision is subject to the receipt by ECHA of the proof that the Claimant has paid the Other Party a share of the costs incurred pursuant to Article 27(6) of the REACH Regulation ('proof of payment'), within two months from the notification of the present decision, i.e. by 31 July 2023.

The reasons for this decision are set out in Annex I.

¹ 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, OJ L 396, 30.12.2006, p.1, as last amended.

² Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 3, 6.1.2016, p.41.

The list of studies covered by the present decision, along with copies of the (robust) study summaries, can be found in Annexes II and III, respectively. However, **the Claimant cannot make use of this permission to refer** to update its registration dossier for the Substance **before submitting to ECHA a proof of payment and before receiving from ECHA an acknowledgment of receipt.**

Provided that the Other Party makes the full study report available to the Claimant, the Other Party shall have a claim on the Claimant for an equal share of the cost it has incurred, which shall be enforceable in the national courts.

If the Claimant does not provide ECHA with a proof of payment within two months from the notification of the present decision, ECHA will issue a decision revoking the present decision. In such case, the Claimant may continue negotiating to reach an agreement with the Other Party. Should these subsequent negotiations fail, the Claimant can submit a new dispute to ECHA.

This decision will be published in an anonymised version on ECHA's website³.

B. Observations

The present decision may not cover all the Claimant's information needs under [REDACTED] of the REACH Regulation.

Despite the present decision, both parties are still free to reach a voluntary agreement. ECHA strongly encourages the parties to negotiate further in order to reach an agreement that will be satisfactory for both of them.

Instructions to the Claimant on how to update their registration making use of the permission to refer are provided in Annex IV.

C. Appeal

Either party may appeal this decision to the Board of Appeal of ECHA within three months of its notification. The appeal must set out the grounds for appeal. Further details, including the appeal fee, are set out at <http://echa.europa.eu/web/guest/regulations/appeals>.

Authorised⁴ by Minna Heikkilä, Head of Legal Affairs

³ Available at <https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach>.

⁴ As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Annex I: REASONS FOR THE DECISION

A. Applicable law

1. In a dispute pursuant to Article 27(5) of the REACH Regulation, ECHA performs an assessment of the efforts of the parties to reach an agreement (Article 5 of Implementing Regulation 2016/9). According to Article 27(6) of the REACH Regulation and Article 3(2) of Implementing Regulation 2016/9, ECHA may grant permission to refer to the requested studies, if the claimant has made every effort to find an agreement on the sharing of the data and the other party has failed to do so. The permission to refer is subject to the proof that the potential registrant has paid a share of the costs incurred by the previous registrant(s).
2. The obligation to make every effort to find an agreement that is transparent, fair and non-discriminatory is laid down in Articles 27(2) and 27(3) of the REACH Regulation. It is further defined in Articles 2 and 4 of Implementing Regulation 2016/9. This obligation applies equally in cases of tonnage band upgrade, pursuant to Article 12(2) of the REACH Regulation.
3. Making every effort means that the registrants must negotiate as constructively as possible and in good faith. They must make sure that the negotiations move forward in a timely manner, express their arguments and concerns, ask questions and reply to each other's arguments, concerns and questions. They must try to understand the other party's position and consider it in the negotiations. Making every effort also means that the parties need to be consistent in their negotiating strategy. They should raise their concerns in a timely manner and behave in a consistent and predictable manner as reliable negotiators. When they face dissent on an aspect, the parties have to explore alternative routes and make suitable attempts to unblock the negotiations. As the potential and existing registrants themselves bear the obligation to make every effort to find an agreement, they need to exhaust all possible efforts before submitting a dispute to ECHA with the claim that negotiations have failed.

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 12 April 2023 and by the Other Party on 2 May 2023.
6. The parties have been communicating on the costs of joining the joint submission for the Substance since 2017. The negotiations subject to the present dispute seem to have started concretely in June 2018, when the Claimant again inquired on the costs for a Letter of Access ('LoA') for the Substance.⁵ In response, the Other Party presented the LoA costs for the different tonnage bands. They referred to a Substance Evaluation decision of [REDACTED], noting that the information request therein "*is relevant to all tonnage bands*". Moreover, the Other Party referred to studies conducted as a result of an ECHA decision on a testing proposal of [REDACTED], stating that "*in the case of an [REDACTED] registration, the study costs of the other/higher tonnage bands must also be distributed pro rata*".⁶

⁵ E-mail from the Claimant; 18/06/2021. The evidence provided attests to a similar request having been made already on 8 June 2017.

⁶ Email from the Other Party; 23/06/2021.

7. The Claimant asked for further information and for a cost breakdown,⁷ which the Other Party provided.⁸ The Claimant then asked for clarifications, specifically why the costs for the [REDACTED] study, required at [REDACTED], would need to be shared at [REDACTED].⁹
8. The Other Party replied to this, indicating that “[d]ue to the adverse effects on [REDACTED] and other concerns in relation with [REDACTED] observed (...), ECHA and [REDACTED] lead registrant agreed to conduct [REDACTED] study to clarify the [REDACTED] of the substance (...). Following this, the higher Tier study, here the [REDACTED], can be shared with co-registrants of lower tonnage bands.”¹⁰
9. The Claimant asked to be excluded from the cost sharing of this study, since the cost was “very high, and [it] only intend[s] to register at [REDACTED]”.¹¹ The Other Party reverted that the “adverse effects of the substance are relevant for all workers” and that “ECHA requested this specific study for the substance itself, independent from the tonnage band”.¹²
10. In June 2022, the Claimant requested the updated LoA fees for the substance¹³ and respective cost breakdown,¹⁴ which the Other Party provided.¹⁵ The Claimant again argued, with reference to ECHA’s Frequently Asked Questions number 1289 and the fact that the testing proposal decision concerned only [REDACTED] registrants, that its client should not bear the cost of the study at issue.¹⁶ In response, the Other Party stated that the study was necessary for the Claimant, noting that “based on ECHA Guidance and the above serious concern described in the very same guidance an [REDACTED] may be proposed on [REDACTED] level. This means you also need this study for your registration to satisfy your registration requirements. Therefore you are also obliged to share the respective costs on the basis of Article 4(1) of the [Implementing] Regulation [2016/9]”.¹⁷ The Claimant responded that “potential registrants of a substance in a low tonnage band do not have to contribute to the cost of a study if this study is not required for a registration in their tonnage band (Article 11(2) REACH)” and asked the Other Party to discuss internally how to proceed.¹⁸
11. The parties continued their discussions, highlighting their disagreement on the need, for the Claimant, to share the cost of the study at issue: the Other Party claiming that cost sharing between the relevant annexes was justified,¹⁹ the Claimant responding its client does not need that data and is “not willing to pay extra money just because the tonnage of the J[oint]S[ubmission] is high”.²⁰ The Claimant thus resorted to asking the Other Party to make an offer for the LoA price for the relevant tonnage band without the study, adding that, if the need arises, they will buy it at a later stage.²¹

⁷ Emails from the Claimant; 11/08/2021, 12/08/2021.

⁸ Email from the Other Party; 12/08/2021.

⁹ Email from the Claimant; 13/08/2021.

¹⁰ Email from the Other Party; 24/08/2021.

¹¹ Email from the Claimant; 25/08/2021.

¹² Email from the Other Party; 25/08/2021.

¹³ Email from the Claimant; 09/06/2022.

¹⁴ Email from the Claimant; 30/06/2022.

¹⁵ Emails from the Other Party; 09/06/2022, 14/07/2022.

¹⁶ Email from the Claimant; 19/07/2022.

¹⁷ Email from the Other Party; 19/07/2022.

¹⁸ Email from the Claimant; 20/07/2022.

¹⁹ Email from the Other Party; 07/09/2022.

²⁰ Email from the Claimant; 08/09/2022.

²¹ Email from the Claimant; 19/09/2022.

12. The Other Party maintained its disagreement and informed the Claimant it would contact ECHA.²² The Claimant again requested that an LoA offer would be made without the study, claiming *"it is against the REACH data-sharing principle that the lead registrant forces the co-registrant to purchase data which the co-registrant believes is not necessary for them"* and that the process would need speeding up, otherwise they would be forced to initiate a dispute before ECHA.²³ The Other Party noted it was still awaiting ECHA's reply, and in the meantime could only *"offer an agreement including the requested study"*.²⁴
13. In the meantime, the Claimant informed the Other Party its client would like *"to register at [REDACTED]"*, and asked for the corresponding agreement and LoA.²⁵ The parties proceeded to reach an agreement for the selected tonnage band.²⁶
14. In December 2022, the Other Party shared the reply received from ECHA, stating that *"ECHA confirmed that [the Other Party] is free to claim compensation from co-registrants for the study requested in the decision, invoking contractual arrangements or the REACH regulation"*. It noted *"the other co-registrants also raised some arguments against cost sharing for this necessary study, but ultimately accepted"*, and in line with Article 4 of Implementing Regulation 2016/9, *"the costs must be shared fairly, transparently and without discrimination"*.²⁷ The Claimant reacted, stating that the information was similar to a reply they had received from ECHA, noting that *"before ECHA's compliance check, [they] have NO 'obligation' to share the cost"* for the study at issue, and it is for them to *"decide whether [they] need this study or not"*. The Claimant thus reiterated the request to exclude the study from the study list in the joint submission agreement.²⁸
15. The Other Party expressed concern that ECHA will not verify whether the study is needed for the Claimant, stating that *"it is not only [the Claimant's] voluntary action to decide whether you need this study or not"*, and reiterating their position.²⁹ The Claimant again noted its client *"still wishes to upgrade the tonnage"*, and so it suggested it could opt-out to address the Other Party's concern, since *"ECHA will individually check all the opt-out dossiers"*. It thus requested *"a quotation for the LoA"* and the robust study summaries.³⁰ The Other Party replied that it *"cannot support an [REDACTED] registration without the discussed [REDACTED] considering all the arguments exchanged in detail during the last months"*; it hence recommended the Claimant use the opt-out function for the update.³¹
16. The Claimant followed up by requesting the *"LoA fees for each standard [REDACTED] endpoint"*, insisting on this request for a period of one month.³² The Other Party eventually replied with reference to their previous correspondence, stating that it would only support the update *"with an amended agreement covering all discussed studies including"* the study under disagreement; otherwise, the Claimant should opt-out.³³ The Claimant agreed, but noted it did not hold the data, so it would need to purchase the studies from the Other Party.³⁴ In the

²² Email from the Other Party; 21/09/2022.

²³ Emails from the Claimant; 22/09/2022, 11/10/2022, 12/10/2022, 13/10/2022.

²⁴ Email from the Other Party; 13/10/2022.

²⁵ Email from the Claimant; 18/10/2022.

²⁶ Emails from Claimant and the Other Party between 18/10/2022 and 02/11/2022.

²⁷ Email from the Other Party; 01/12/2022.

²⁸ Email from the Claimant; 08/12/2022.

²⁹ Email from the Other Party; 21/12/2022.

³⁰ Email from the Claimant; 04/01/2023.

³¹ Email from the Other Party; 11/01/2023.

³² Emails from the Claimant; 17/01/2023, 08/02/2023; 14/02/2023, 21/02/2023.

³³ Email from the Other Party; 21/02/2023.

³⁴ Email from the Claimant; 22/02/2023.

absence of a reply from the Other Party, the Claimant proposed its own calculation of the LoA costs, but the Other Party remained silent.³⁵

17. On 12 April 2023, the Claimant submitted a dispute claim to ECHA.

C. Assessment

18. In the present negotiations, the disagreement between the parties concerns only the sharing of the cost of [REDACTED], normally required under [REDACTED] of the REACH Regulation.

19. The Claimant argued that the information required for the upgrade of its dossier to [REDACTED] (corresponding to its desired tonnage band) excludes the information required under [REDACTED]. Therefore, it requested the LoA to be limited to the list of studies required under [REDACTED] without that particular study. The Other Party maintained that the study was necessary to fulfil the information requirements also at [REDACTED] and was therefore necessary for the Claimant's registration to be compliant. Therefore, it requested cost sharing for the higher-tier study costs.

20. In response, the Claimant reiterated it did not need such data to fulfil its information requirements and that the Other Party could not force cost-sharing for data which had not been requested. In essence, the Claimant raised two arguments:

- a. each registrant need only comply with the information requirements for the purposes of registration within the desired tonnage band;
- b. the Claimant would take full responsibility for the compliance of its own dossier.

21. In view of the Other Party's insistence, the Claimant tried to move forward with the negotiations despite the disagreement, by requesting an agreement for a lower tonnage band first, and by suggesting it could submit an opt-out dossier in order to address the Other Party's compliance concerns. The Other Party, however, remained firm in its condition of either sharing the whole list of studies it considered relevant for the requested price, or simply not sharing data, as is apparent from their messages and eventual lack of reply to the Claimant's successive communication attempts after 21 February 2023.

a. Sharing of data and its costs limited to the information required

22. Article 27(1) of the REACH Regulation establishes that potential registrants (or existing registrants in case of a tonnage band upgrade, as prescribed by Article 12(2)) must request from previous registrants the information they require in order to register. Article 27(2) provides that the obligation, for the parties, to make every effort to reach an agreement relates to sharing the information requested by the potential registrant. Article 27(3) further specifies that "[r]egistrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements".

23. In addition, Recital 5 to Implementing Regulation 2016/9 states that "*both administrative costs and costs related to information requirements should only be shared where those costs are relevant to the information that a party is obliged to submit for registration under [the REACH] Regulation*".

24. As described above, the Claimant clearly defined the scope of the information it considered necessary to fulfill its information requirements and requested the cost for such information.

³⁵ Emails from the Claimant; 23/02/2023, 28/02/2023, 01/03/2023, 15/03/2023, 05/04/2023.

By refusing to share the data specifically requested by the Claimant, the Other Party failed to make every effort to reach an agreement.

b. Responsibility for compliance

25. The data sharing dispute procedure relates to the sharing of the data requested and its costs. Dossier compliance, on the other hand, is performed by ECHA under Title VI of the REACH Regulation, pursuant to Articles 40 and 41, in an independent process concerning evaluation. Previous registrants do not have any competence under the REACH Regulation (neither under Articles 40 and 41, nor Article 27) to assess compliance.
26. The reason invoked by the Other Party to refuse sharing the requested data relates to the suspected non-compliance of the Claimant's dossier with an information requirement set out in an annex, but allegedly triggered at the Annex applicable to him. However, issues pertaining to dossier compliance do not fall within the scope of the parties' every effort regarding data sharing. It is, however, for each and every registrant to assess its own data needs, regarding the necessary information requirements.
27. By refusing to share only the data requested by the Claimant using a justification based on the compliance of the Claimant's dossier with an information requirement set out in a higher Annex, the Other Party failed to make every effort to reach an agreement.

D. Conclusion

28. The Claimant made every effort to reach an agreement on the sharing of information.
29. Therefore, ECHA grants the Claimant permission to refer to the studies specified in the Annex II, subject to the receipt by ECHA of the proof that the Claimant has paid the Other Party a share of the costs incurred. This proof of payment must be submitted to ECHA by 31 July 2023. In case it is not submitted by the indicated date, the present permission to refer will be revoked.