


11 October 2021*The Claimant*Copy to:
The Other Party**Sent via REACH-IT**Decision number:
Dispute reference number:
Name of the substance (the 'Substance'):

EC number of the Substance:

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 13 December 2021.

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

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 submit a registration dossier for the Substance

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.

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 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 parties.

Instructions to the Claimant on how to submit a registration dossier 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 the procedure pursuant to Article 27(5) of the REACH Regulation, ECHA performs an assessment to determine whether the parties made every effort to reach an agreement on the sharing of information and associated costs for the purposes of registration. In doing so, ECHA checks whether the parties' obligations related to the sharing of data and data costs have been complied with, including whether the parties complied with the requirements of fairness, transparency and non-discrimination (Article 5 of Implementing Regulation 2016/9). 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.
3. Specifically, Article 27(3) of the REACH Regulation and Article 2 of Implementing Regulation 2016/9 provide for the requirement for data and cost sharing to be transparent. Article 2(1)(a) and (2) of Implementing Regulation 2016/9 requires a previous registrant to provide to a potential registrant, upon request, with an *'itemisation of data to be shared, including the cost of each data item, a description indicating the information requirements in the REACH Regulation to which each cost corresponds and a justification of how the data to be shared satisfies the information requirement'*⁵. Under the last subparagraph of Article 2(2) of Implementing Regulation 2016/9, the previous registrant is expected to provide this information to the potential registrant *'without undue delay'*.
4. The parties 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. In doing so, each party must clearly state his or her requests of information, and ensure that the other party has had enough time to provide an answer before concluding that the negotiations have failed.

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 25 August 2021 and by the Other Party on 15 September 2021.
6. During the negotiations most e-mail messages were exchanged between the Other Party, on one side, and a consultant acting on behalf of the Claimant, on the other side. For the sake of simplicity, however, no distinction is made below between the Claimant and the Claimant's representative, and only the Claimant is referred to as taking part in the exchange.
7. On 23 February 2021, the Claimant contacted for the first time the generic e-mail address of the Other Party, requesting the price of a Letter of Access ('LoA') for the [REDACTED] and [REDACTED] tonnage bands, the Substance Identity Profile ('SIP') and the cost of the Chemical Safety Report ('CSR').⁶ Prior to such e-mail, in the course of February, the Claimant had sent

⁵ Article 2(1)(a) of Implementing Regulation 2016/9.

⁶ E-mail message of the Claimant of 23 February 2021.

several messages to individual e-mail addresses of employees of the Other Party, without receiving any substantive reply.⁷

8. On 2 and 3 March 2021, the Other Party provided the requested information on the LoA, indicating that the price could slightly change due to parallel negotiations with another potential registrant.⁸ In addition, the Other Party clarified that the CSR would be made available by the lead registrant, and requested the Claimant to provide the composition of its substance of interest, so that the Other Party could verify whether it fell within the SIP.⁹
9. Upon receipt of the above information, on 3 March 2021, the Claimant indicated that they would get back to the Other Party in case the Claimant needed additional details or decided to proceed with the purchase of the LoA.¹⁰
10. On 16 April 2021, the Claimant contacted again the Other Party stating that the Claimant intended to proceed with a co-registration for the Substance in the [REDACTED] tonnage band. The Claimant also asked clarifications on the coverage and the cost of the CSR, and invited the Other Party to make its SIP available.¹¹
11. On 26 April 2021, the Claimant provided its own SIP to the Other Party,¹² after the latter reiterated its request citing internal procedural requirements¹³.
12. After the above e-mail exchange, in the absence of any follow-up from the Other Party, the Claimant sent three separate reminders on 6 May, 20 May and 9 June 2021. In the last reminder, the Claimant indicated that it would submit a complaint to ECHA, should the Other Party remain unresponsive over the following 48 hours.¹⁴
13. On 9 June 2021, the Other Party reacted stating that the parties' SIPs were comparable and asked the Claimant's details in order to prepare the invoice and the SIEF ('Substance Information Exchange Forum') agreement.¹⁵
14. On 24 June 2021, the Claimant requested the itemisation of the costs of the LoA for the [REDACTED] tonnage band and provided details for the preparation of the SIEF agreement.¹⁶ The Claimant also asked clarifications with respect to the classification of the Substance.¹⁷
15. In the absence of any response, the Claimant sent reminders to the Other Party on 2 and 20 July 2021. In its second reminder, the Claimant indicated that it would submit a complaint to ECHA if the Other Party would not respond by the end of that week.¹⁸
16. On 11 August 2021, the Other Party reacted indicating that that *'[t]he total cost of the LoA was calculated taking into account: data and studies; Scientific and technical preparation of the Joint Registration Dossier; Administrative costs; Inflation (3%/year); LR hourly living*

⁷ E-mail messages of the Claimant of 4, 15 and 18 February 2021.

⁸ E-mail messages of the Other Party of 2 and 3 March 2021.

⁹ E-mail message of the Other Party of 3 March 2021.

¹⁰ E-mail message of the Claimant of 3 March 2021, 11:36.

¹¹ E-mail message of the Claimant of 16 April 2021.

¹² E-mail message of the Claimant of 26 April 2021.

¹³ E-mail message of the Other Party of 23 April 2021.

¹⁴ E-mail messages of the Claimant of 6 May, 20 May and 9 June 2021.

¹⁵ E-mail message of the Other Party of 9 June 2021.

¹⁶ E-mail message of the Claimant of 24 June 2021, 16:40.

¹⁷ E-mail message of the Claimant of 24 June 2021, 17:14.

¹⁸ E-mail messages of the Claimant of 2 July 2021, 17:12 and 17:13, and 20 July 2021.

*expenses*¹⁹. The Other Party also informed that the Claimant would have to contact separately a third party in order to negotiate access to two specific studies. The contact details of the third party were provided. The Other Party requested the Claimant to confirm their interest in purchasing the LoA and indicated that, if so, they would provide the template of a *'Non-Disclosure Agreement'* before sending the data.²⁰

17. On the same day, the Claimant confirmed its interest in purchasing the LoA but pointed out that, prior to that, certain points would need clarification from the Other Party. Specifically, the Claimant asked confirmation of the total cost of the LoA as well as clarifications on the need to purchase a separate LoA from a third party, highlighting that this was *'new information as this was not mentioned by [the Other Party] in any of [the parties'] previous communication'*²¹. In addition, the Claimant reminded the Other Party of the query on the classification of the Substance, and requested the *'Non-Disclosure Agreement'* template for review by the Claimant's legal team. The Claimant also repeated that they kept the option of contacting ECHA open, including requesting a token, and asked the Other Party to respond to all pending questions by the end of that week.²²
18. On 20 August 2021, the Other Party sent the SIEF agreement template and SIP to the Claimant. The Other Party indicated that the issue concerning the classification of the Substance was still under discussion, while answers to all other questions by the Claimant could be found inside the agreement template. The contact person of the Other Party informed that he would be out of office during the following week, and any other exchange would be possible only from 31 August 2021 onwards.²³
19. On 25 August 2021, the Claimant lodged the present claim.

C. Assessment

20. As explained in section A, ECHA is called upon to determine whether the parties complied with their obligations related to the sharing of data and data costs in the negotiations outlined in section B.
21. In that context, the Agency assessed the first criterion laid down in Article 2(2) of Implementing Regulation 2016/9, namely whether the agreement was negotiated in accordance with the transparency requirement.²⁴
22. In addition, when carrying out its assessment, the Agency must pay due regard to all individual actions and communications of the parties as well as the development of the negotiations over time.²⁵ Finally, the Agency's assessment centres upon those elements on which the parties could not agree during their negotiations, and which therefore led to the filing of the case.²⁶
23. In the present case, the Claimant repeatedly complained about the delayed responsiveness of the Other Party. The Agency will therefore verify the parties' compliance with their data sharing obligations against the requirements set out above, namely whether the Other Party

¹⁹ E-mail message of the Other Party of 11 August 2021.

²⁰ *Ibid.*

²¹ E-mail message of the Claimant of 11 August 2021.

²² *Ibid.*

²³ E-mail message of the Other Party of 20 August 2021.

²⁴ See, to this effect, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, Decision of the Board of Appeal of 15 April 2019, paragraph 85.

²⁵ *Ibid.*, paragraph 87.

²⁶ *Ibid.*, paragraph 88.

provided the Claimant with the cost itemisation '*without undue delay*' as required by Article 2(2) of Implementing Regulation 2016/9.

24. After their initial message of 23 February 2021, on 16 April 2021 the Claimant confirmed its interest in proceeding with a co-registration for [REDACTED]. On 26 April 2021, the Claimant further provided the requested SIP to the Other Party for comparison. On 9 June 2021, after three separate reminders from the Claimant in the course of May and June, the Other Party finally reacted confirming the comparability of the parties' SIPs. On 24 June 2021, the Claimant requested the itemisation of the costs of the LoA for its tonnage band of interest, but it was not until 11 August 2021, following two separate reminders, that the Other Party finally reacted to the Claimant's request.
25. The cost breakdown provided by the Other Party on 11 August 2021 appears generic, as it merely consisted of a list of items covered by the proposed figure, without any specification of the cost associated with each item and no justification on how the data to be shared satisfied information requirements. Furthermore, what appeared to be of concern to the Claimant was the revelation by the Other Party, at a late stage of the negotiations, that the Claimant would have to negotiate a separate access to two studies with a third party. This raised additional questions from the Claimant, which only received a tentative answer by the Other Party on 20 August 2021. Finally, in this last communication, the Other Party indicated its unavailability for further discussion until the end of August, without offering an alternative contact to allow the negotiations to progress.
26. Therefore, the parties have not reached a common understanding on the itemisation of costs for more than two months following the initial request of the Claimant, due to the delayed responsiveness of the Other Party.
27. It follows that the Other Party did not comply with the requirement of providing the itemisation of costs to the Claimant '*without undue delay*', as required by Article 2(2) of Implementing Regulation 2016/9.
28. As a result, the breach of the transparency obligation by the Other Party made it impossible for the Claimant to constructively engage in the discussion, and for both parties to achieve a data sharing agreement for the tonnage band of interest to the Claimant in a timely fashion.
29. This case refers to information requested to the Other Party by the Claimant for a registration in the [REDACTED] tonnage band.²⁷

D. Conclusion

30. The Other Party failed to comply with its obligations with a view to achieve an agreement on the sharing of information and associated costs, as provided for by Article 2(2) of Implementing Regulation 2016/9.
31. Therefore, ECHA grants the Claimant permission to refer to the studies specified in 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 13 December 2021. In case it is not submitted by the indicated date, the present permission to refer will be revoked.

²⁷ E-mail messages of the Claimant of 16 April and 24 June 2021.