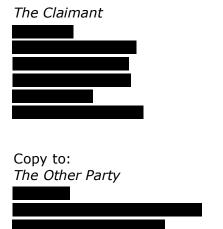


9 January 2024



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 11 March 2024.

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 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 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 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

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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.
- 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 16 November 2023. The Other Party did not submit any evidence by the set deadline, 8 December 2023. Therefore, the assessment has been conducted solely on the basis of the information provided by the Claimant.

5.	On 21 June 2023, the Claimant contacted the lead registrant for the Substance indicating that
	they wished to update their tonnage band from
	and enquiring as to the costs of the Letter of Access for such an update. The lead
	registrant responded on 23 June 2023 stating that the joint submission only covered the
	tonnage band meaning the requested tonnage band was not covered. The evidence
	suggests that the Claimant and lead registrant discussed the issue further via a phone call on
	26 June 2023, during which it became apparent that all members of the joint submission in
	the tonnage band had submitted information separately, pursuant to Article
	11(3) of the REACH Regulation ("opt-out").7

7. On 24 July 2023, the Claimant contacted two of the other members of the joint submission who had registered in the tonnage band to enquire about access to the relevant data needed to update their registration.⁸ Both members replied that the Other Party was the owner of the data (and not a member of the joint submission) and that they could not share

 $^{^{5}}$ E-mail from Claimant to lead registrant dated 21 June 2023.

⁶ E-mail from lead registrant to Claimant dated 23 June 2023.

⁷ E-mail from Claimant to lead registrant dated 26 June 2023.

⁸ E-mail from Claimant to dated 24 July 2023; E-mail from Claimant to dated 24 July 2023.



the data they had obtained from the Other Party.⁹ On 5 September 2023, the Claimant contacted the representative of a third member of the joint submission with a registration in the tonnage band of interest to them, but their enquiry went unanswered.¹⁰

- 8. The Claimant contacted the Other Party on 24 July 2023 asking for the costs of the studies needed to update their registration to ______, including the cost sharing structure.

 The Claimant further requested a number of studies that they qualified as being older than twelve years. On the same day, the Other Party replied that they did not have a registration for the Substance and therefore could not help the Claimant.

 The Claimant noted in response (on the same day) that even though the Other Party was correct, they were listed by ECHA as the data holder for at least one of the studies mentioned.
- 9. In parallel with these discussions, the Claimant requested on 9 August 2023 the Letter of Access price from the Other Party for the tonnage band for one of its affiliate companies. The Other Party responded on 21 August 2023 requesting further details regarding the corporate relationship between the Claimant and this affiliate company. The Claimant provided the requested information on the same day and further referred to phone discussions with the Other Party about the possibility "to supply the IUCLID file for the REACH registration" for the Substance for a small fee. The Claimant explained that if this were not possible, they would have to use one of the other companies in their corporate group to register the Substance at
- 10. Despite numerous reminders after this date, including a letter from the Claimant's external legal counsel reminding the Other Party of its data sharing obligations and requesting the data to be provided,¹⁷ the Other Party failed to respond. The Claimant notified the Other Party of its intention to file a dispute with ECHA on 1 November 2023 if the studies required to submit their tonnage update were not received by that date.¹⁸ The dispute was submitted on 9 November 2023, and completed on 16 November 2023.

C. Assessment

- 11. 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.
- 12.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. ¹⁹ Finally, the Agency's assessment centres upon those elements on

⁹ E-mail from to Claimant dated 31 July 2023; E-mail from to Claimant dated 25 July 2023.

¹⁰ E-mail from the Claimant to dated 5 September 2023.

¹¹ E-mail from Claimant dated 24 July 2023.

¹² E-mail from Other Party dated 24 July 2023.

¹³ E-mail from Claimant dated 24 July 2023.

¹⁴ E-mail from Claimant dated 9 August 2023.

¹⁵ E-mail from Other Party dated 21 August 2023.

¹⁶ E-mail from Claimant dated 21 August 2023.

 $^{^{17}}$ Letter from Claimant's external legal counsel dated 12 October 2023; E-mail from Claimant on 29 August 2023; E-mail from Claimant on 5 September 2023.

¹⁸ E-mail from Claimant dated 1 November 2023.

¹⁹ See, to this effect, Decision of the Board of Appeal of 15 April 2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, paragraph 87.



which the parties could not agree during their negotiations, and which therefore led to the submission of the dispute claim. 20

- 13. In the present case, there was no disagreement between the Claimant and the Other Party with regard to the identification of the data to be shared, its cost or any other related condition. However, the parties never came to a point of exchanging a data sharing agreement on the Substance. In fact, the negotiations never really progressed beyond a couple of email exchanges. However, during those few exchanges, the Other Party informed the Claimant that it could not assist them with their update request on the basis that the Other Party was not a registrant for the Substance. ECHA understands that, by this statement, the Other Party implied that it did not have any obligations to share data with the Claimant under the REACH Regulation.
- 14. The obligations specified under Article 27(2) of the REACH Regulation to share data and to make every effort to come to an agreement indeed apply to <u>potential and previous registrants</u> of the same substance. In this case, the Other Party holds a valid registration for the Substance. According to the information in ECHA's database, the Other Party had notified the Substance under the Notification of New Substances scheme of Directive 67/548/EEC and claimed the registration number that was assigned to that notification²¹ in March 2009. At the time of the dispute submission, the Other Party's registration status for the Substance was 'active'. As such, the Other Party is a previous registrant that was subject to the obligations specified under Article 27 of the REACH Regulation when the Claimant made their request for the information required for their registration update.
- 15. As regards the negotiations, the Claimant sent a number of emails (including a letter from their external legal counsel) to the Other Party explaining their situation and requesting the information they required to update their registration. Despite the Claimant's continued efforts, the Other Party, at first, refused to provide the information and then simply failed to respond. In the light of the Other Party's lack of reply, the Claimant noted the possibility of a dispute claim with ECHA in case the Other Party failed to respond to their request. Finally, the Claimant contacted the lead registrant for the substance, as well as three other members of the joint submission who had registered in the without success.
- 16. For their part, the Other Party essentially refused to engage in negotiations, based on the misconception that they did not have any data sharing obligations, and then failed to reply to the Claimant's reminders.
- 17. Based on the available evidence, the Claimant made every effort that could reasonably be expected in the circumstances of the case. On the other hand, the lack of co-operation and response from the Other Party made it impossible to achieve a data sharing agreement for the tonnage band of interest to the Claimant.

D. Conclusion

- 18. The Claimant made every effort to reach an agreement on the sharing of information, pursuant to Article 27(2) and (3) of the REACH Regulation, whilst the Other Party failed to do so.
- 19. 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

²⁰ *Ibid*, paragraph 88.

 $^{^{21}}$ In accordance with Article 24 of the REACH Regulation. The Other Party's registration number is



share of the costs incurred. This proof of payment must be submitted to ECHA by 11 March 2024. In case it is not submitted by the indicated date, the present permission to refer will be revoked.