

[REDACTED]
30 May 2022

The Claimant

[REDACTED]

Copy to:
*The Other Party*¹

[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')² 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')³,

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,

¹ ECHA notes that there has been a change in Only Representative after the negotiations came to an end. For the purposes of this decision and its Annexes, 'Other Party' shall refer to both.

² 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.

³ 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.

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 1 August 2022.

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 **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 website⁴.

B. Observations

The present decision may not cover all the Claimant's information needs under Annexes VII-IX 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>.

Authorised⁵ by Minna Heikkilä, Head of Legal Affairs

⁴ Available at <https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach>.

⁵ 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). (Robust) study summaries submitted at least twelve years previously are not subject to cost sharing under Article 27 of the REACH Regulation.
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 13 April 2022 and by the Other Party on 3 May 2022.
6. The negotiations started in 2021, between the Claimant and the Other Party, an Only Representative for a non-EU manufacturer ('the client').⁶
7. On 21 December 2021, the Claimant asked the Other Party for the Letter of Access ('LoA') costs for the tonnage bands [REDACTED] tonnes per annum ('tpa') for the Substance.⁷ On 30 December 2021, the Other Party suggested the Claimant submit an inquiry to ECHA, after which it would be able to determine for which studies the LoA should be prepared, and proceed accordingly.⁸

On 25 January 2022, the Claimant forwarded to the Other Party ECHA's communication regarding the inquiry, reiterating its request for a draft LoA, 'including the cost overview for the tonnage band [REDACTED]'. The Claimant noted that in the co-registrant page in REACH-IT there was an indication that most of the studies were older than 12 years, as '[the Other Party] mentioned in [their] meeting'.⁹ The Other Party reacted on the same day,

⁶ See footnote 1.

⁷ Claimant; email of 21/12/2021

⁸ Other Party; email of 30/12/2021

⁹ Claimant; email of 25/01/2022

saying it would transmit the information about the successful inquiry to the client. It further stated it would 'take a look at the data that are over the 12 year rules and check internally on how to prepare the LoA'.¹⁰

8. On 28 January 2022, the Other Party sent to the Claimant a 'draft report on the sameness evaluation', asking it to review the document and 'send an approval for finalization of the report'.¹¹ On 1 February 2022, the Claimant enquired about the progress of the LoA.¹² On 10 February 2022, the Other Party informed the Claimant that they were awaiting information from the client on costs to prepare the LoA. It noted that for the studies submitted more than 12 years ago, the cost would be only related to consultancy and other costs to maintain the registration.¹³ On the same day, the Other Party asked the Claimant to confirm the tonnage band requested, since its registration covered the tonnage band [REDACTED]. It added that it was of the view the Claimant would also need 'the LoA for the [REDACTED] tonnage [REDACTED]'.¹⁴
9. On 16 February 2022, the Claimant reacted to the 'draft sameness check report'. It asked for clarifications in relation to the strategy for evaluation of the substance sameness, particularly with regard to the indicated 'deviations of the two substances'.¹⁵
10. On 24 February 2022, the Other Party informed the Claimant that it had sent the 'Cooperation agreement' to its client, stating it had asked 'for a time line for the review of the LoA costs and approval for the agreement', but had received no answer.¹⁶ The Claimant replied on the same day, asking the Other Party to 'apply some pressure from [its] side to the client'.¹⁷
11. On 25 February 2022, the Other Party informed the Claimant that 'the LoA costs and the Cooperation agreement [was] under review of [the] client'. It noted a deadline had been set to that effect and that it had explained to the client 'the obligation of data sharing with potential members in a timely manner'.¹⁸
12. On 7 March 2022, the Claimant asked the Other Party for updates.¹⁹ The Other Party replied on 13 March 2022, stating it had discussed the substance sameness with the client, and that there were 'some doubts about the substance sameness'. It informed the Claimant that 'a request [would] be made to ECHA for a consultation on the substance sameness', hence it would not be able to immediately provide 'the LoA calculation and the Cooperation Agreement'. It further asked the Claimant to share its substance's identity, 'to compare not only the main constituents but also the impurities with the composition of [its] client'.²⁰
13. On 14 March 2022, the Claimant expressed its disappointment with the Other Party's course of action, in view of the results of the inquiry with ECHA. It therefore asked for a meeting with the Other Party's management team, noting it would otherwise 'file an official complaint to ECHA'.²¹

¹⁰ Other Party; email of 25/01/2022

¹¹ Other Party; email of 28/01/2022

¹² Claimant; email of 01/02/2022

¹³ Other Party; email of 10/02/2022, 13:03

¹⁴ Other Party; email of 10/02/2022, 15:24

¹⁵ Claimant; email of 16/02/2022

¹⁶ Other Party; email of 24/02/2022

¹⁷ Claimant; email of 24/02/2022

¹⁸ Other Party; email of 25/02/2022

¹⁹ Claimant; email of 07/03/2022

²⁰ Other Party; email of 13/03/2022

²¹ Claimant; email of 14/03/2022

14. On 18 March 2022, the Other Party told the Claimant it had contacted ECHA and was awaiting a reply.²² On 23 March 2022, it informed the Claimant that it had received a reply from ECHA and sent 'an explanation to [the] client about the substance sameness', stating it 'endorsed the outcome of ECHA and therefore advised [the] client to follow up the outcome of the inquiry and share the LoA costs and the Cooperation Agreement'. It further attached a 'mask Cooperation Agreement', asking the Claimant to comment, and promising an update 'by Friday 25 March'.²³
15. On 24 March, the Other Party noted it would have a meeting with the client the day after.²⁴ On 25 March 2022, the Other Party came back to the Claimant, stating the meeting with the client could not take place on the planned date, and hence it could not 'share the LoA costs and the Cooperation Agreement' since it was 'contractually bound to have [the] client's approval'. It promised to revert to the Claimant with 'a definitive answer before April 1, 2022'.²⁵
16. On 1 April 2022, the Other Party informed the Claimant that it had not 'been able to come to an agreement with [the] client'.²⁶ On 6 April 2022, the Claimant expressed its discontent, and stated it would 'file a data sharing dispute to ECHA'.²⁷ The dispute was submitted on that date, and completed on 13 April 2022.

C. Assessment

17. Pursuant to Article 27(2) of the REACH Regulation, when a request for information has been made under this provision, the parties must make every effort to reach an agreement.
18. The Claimant made a clear request for the LoA for the Substance. At the Other Party's invitation, it submitted an inquiry to ECHA pursuant to Article 26 of the REACH Regulation, the results of which it shared with the Other Party. In addition, the Claimant raised questions and required explanations for the doubts expressed by the Other Party with regard to the substance sameness, explaining its own position.
19. Conversely, the Other Party, while always reacting in a timely manner to the Claimant's communications, failed to explain why data sharing was not possible on the basis of the substance sameness discussion. More specifically, it did not provide the clarifications requested by the Claimant on 16 February 2022 on the supposed 'deviations' between the substances and in its request for updates on these matters of 7 March 2022.
20. Later factual elements corroborate the legitimacy for the Claimant to obtain clarifications on the supposed 'deviations' between the substances. Firstly, ECHA's reply to the consultation of the Other Party on this matter, as reported in its email of 23 March 2022. As explained in the same email, it is also the Other Party's own advice to its client to recognise the outcome of ECHA's assessment and to accept the Claimant's data sharing request. In spite of all these elements confirming the absence of substance sameness concerns, the Other Party refused to provide further clarifications and share the requested data.
21. The explanation that the Other Party was bound by the contractual arrangements with its client does not excuse the absence of efforts to justify the refusal to share the data, and does

²² Other Party; email of 18/03/2022

²³ Other Party; email of 23/03/2022

²⁴ Other Party; email of 24/03/2022

²⁵ Other Party; email of 25/03/2022

²⁶ Other Party; email of 01/04/2022

²⁷ Claimant; email of 06/04/2022

not exonerate the Other Party and its client from their joint responsibility in fulfilling their data sharing obligation.

D. Conclusion

22. The Claimant made every effort to reach an agreement on the sharing of information. ECHA notes that, while the Claimant requested information for the tonnage bands [REDACTED], the Other Party made clear that its registration covered only the tonnage band [REDACTED].
23. In light of this, ECHA grants the Claimant permission to refer to the studies specified in Annex II (ie., all the information contained in the dossier, pursuant to Article 27 of the REACH Regulation), 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 1 August 2022. In case it is not submitted by the indicated date, the present permission to refer will be revoked.