

[REDACTED]
Helsinki, 29 August 2018

The Claimant

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

Copy to:

The Other Party

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

Decision number:

Dispute reference number:

Name of the substance (the 'Substance'):

EC number of the Substance:

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

DECISION ON A DISPUTE RELATED TO ACCESS TO A JOINT SUBMISSION AND THE SHARING OF DATA

A. Decision

ECHA grants you permission to refer to the information you requested from the Existing Registrant of the Substance and access to the joint submission.

This decision is adopted under Articles 30(3) and 11 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.

The reasons for this decision are set out in Annex I. The list of studies that ECHA grants you permission to refer to, along with copies of the (robust) study summaries, can be found in Annexes II and III, respectively. Instructions on how to submit your registration dossier are provided in Annex IV.

¹ Regulation (EC) N° 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.

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

B. Observations

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

According to Article 30(3) of the REACH Regulation, the Existing Registrant shall have a claim on you for an equal share of the cost, which shall be enforceable in the national courts, provided that the full study report or reports (if applicable) are made available to you.

Furthermore, please note that with the present decision ECHA gives you a permission to refer to studies only involving tests on vertebrate animals. However, the obligation of a SIEF member to share data on request by another SIEF member also extends to data not related to vertebrate animals.

ECHA will inform the competent national enforcement authorities of the present decision. The national enforcement authorities may take enforcement actions according to Articles 30(6) and 126 of the REACH Regulation.

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. If an appeal is submitted, this decision will be suspended. Further details, including the appeal fee, are set out at <http://echa.europa.eu/web/guest/regulations/appeals>.

Yours sincerely,

Christel Schilliger-Musset⁴

Director of Registration

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 decision has been approved according to the ECHA's internal decision-approval process.

Annex I: REASONS FOR THE DECISION

A. Applicable law

1. When a dispute is submitted to ECHA pursuant to Article 30(3) of the REACH Regulation, ECHA performs an assessment of the parties' efforts to reach an agreement (Article 5 of the Implementing Regulation 2016/9). According to Article 30(3) of the REACH Regulation and Article 3(2) of the Implementing Regulation 2016/9, ECHA may grant permission to refer to the relevant vertebrate studies and access to the joint submission, if the claimant has made every effort to find an agreement on the sharing of the data and access to the joint submission and the other party has failed to do so.
2. The obligation to make every effort to find an agreement on the sharing of data that is fair, transparent and non-discriminatory is laid down in Article 30(1) of the REACH Regulation. It is further defined in Articles 2 and 4 of the Implementing Regulation 2016/9. Under Article 11 of the REACH Regulation, multiple registrants of the same substance must submit data jointly.
3. Making every effort means that the existing and potential 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 each other'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.
4. In particular, every effort means to reply to the requests of the counter party regarding information or other relevant documentation necessary to move forward with the negotiations in a fair, transparent and non-discriminatory way.

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 28 May 2018. The Other Party did not provide any evidence, despite ECHA's initial request, sent on 29 May 2018, and two follow-up communications dated 13 June and 27 June 2018, with an extended deadline for submission set for 5 July 2018 (the original deadline was set for 18 June 2018).
6. On 7 May 2018, the Claimant informed the Other Party that one of the Claimant's clients was *'interested in the registration of [the Substance] in the tonnage band [REDACTED]* and inquired about the Letter of Access ('LoA') cost for that tonnage band.
7. On 14 May 2018, the Claimant contacted the Other Party and inquired as to whether there was *'any news about [the Claimant's] request?'*
8. On 18 May 2018, the Claimant sent an email to the Other Party noting that the Other Party, as the lead registrant of the Substance, is obliged to provide the LoA to a potential registrant. The Claimant inquired again about the LoA for the tonnage band [REDACTED] and asked the Other Party to share the substance identity profile *'asap'*. On the same day, the Claimant sent a follow-up email correcting the tonnage band to [REDACTED].
9. On 28 May 2018, the Claimant informed the Other Party of their intention to file a data-

sharing dispute, as they had not 'receive[d] any answer from [the Other Party's] side (first mail three weeks ago)'.

10. On 28 May 2018, the Claimant submitted a claim under Article 30 of the REACH Regulation, concerning the failure to reach an agreement on access to the joint submission and the sharing of information with the Other Party.

C. Assessment

11. As explained in section A, ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B.
12. Making every effort means that an existing registrant needs to address requests from a potential registrant to reach a data-sharing agreement in a fair, transparent and non-discriminatory manner. According to the Commission Implementing Regulation 2016/9, an existing registrant is expected to react to a potential registrant's request to obtain relevant information and provide an itemisation of costs without undue delay.
13. The provision of costs related to data and administration is the starting point for any data-sharing negotiations. The existing registrant needs to make every effort to provide information to a potential registrant to allow them to understand the costs. Making every effort in the negotiations entails that an existing registrant takes into account the urgency for the potential registrant to register in light of an approaching registration deadline, and does not delay sending relevant information, such as a cost breakdown.
14. ECHA notes that the Claimant started negotiating on only 7 May 2018 and submitted the dispute three weeks after their initial attempt to contact the Other Party; however, such submission appears as a measure of last resort in view of the complete lack of reaction of the Other Party.
15. The Claimant made efforts to obtain the requested information from the Other Party on several occasions. After attempting to make contact on 7 May 2018, the Claimant sent two reminders, dated 14 May and 18 May 2018, having not received any reply from the Other Party to their initial inquiry. Therefore, the Other Party ignored the fact that the Claimant was under objective urgency to progress with their registration due to the approaching registration deadline.
16. ECHA notes that by not providing the requested information and by ignoring all of the Claimants' emails, the Other Party denied the Claimant the possibility to progress negotiations or proceed with their registration.
17. In light of the Other Party's complete inaction, the Claimant could not have made any more efforts to reach an agreement with the Other Party.

D. Conclusion

18. The Claimant made every effort to reach an agreement on access to the joint submission and the sharing of information, whereas the Other Party failed to comply with their obligation to come to an agreement by not making any effort at all.
19. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies specified in Annex II.

"ECHA reminds you that following Article 16 of Regulation (EC) No 1049/2001, the documents attached are subject to copyright protection."