

[REDACTED]

Helsinki, 16 July 2018

The Claimant

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

Represented by

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

Copy to:
The Other Party

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

Represented by

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

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 ACCESS TO A JOINT SUBMISSION AND THE SHARING OF DATA

a. Decision

ECHA grants you the 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

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.

on joint submission of data and data-sharing in accordance with REACH ('Implementing Regulation 2016/9')².

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

This decision will be published in an anonymised version on ECHA's website.³

b. Observations

ECHA reminds both parties that despite of 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(s) is made available to you.

Furthermore, please note that with the present decision ECHA only gives you a permission to refer to studies 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 of 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

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.

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 OF 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 a 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 the 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 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 the 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 a 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 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 6 April 2018. The Other Party did not provide evidence upon ECHA's request.
6. ECHA notes from the context of the submitted by the Claimant evidence that the exchange of emails between the Claimant and the Other Party started before 29 May 2017 (the official start of negotiations based on evidence submitted to ECHA). However, the original emails/communication letters before that date were not submitted to ECHA neither by the Claimant nor by the Other Party.
7. On 29 May 2017, the Other Party apologized for the delay in replying to the Claimant and sent information regarding the Substance Identity Profile and the costs to join the joint submission for the tonnage bands [REDACTED] and [REDACTED]. The Other Party also informed about the existence of a reimbursement system.⁵
8. On 8 June 2017, the Claimant informed the Other Party that they would like to register the substance and requested the substance identity profile (SIP) document to check the sameness of the substance. Additionally, the Claimant informed that as soon as the Other Party would

⁵ Other Party; 29 May 2018.

send them the Letter of Access, they would start with the registration process.⁶

9. On 24 July 2017, the Claimant informed the Other Party that they would like to submit their registration as soon as possible and requested the documents of the Letter of Access and the invoice in order to proceed.⁷
10. On 27 February 2018, the Claimant sent by postal mail a formal request to join the joint submission, and requested to have the conditions and price of the Letter of Access for [REDACTED] as soon as possible. The letter also mentioned that in accordance with Articles 11(1) and 19(1) of the REACH Regulation, '*some of the information referred in Articles 10 and 12 of REACH regulation must be submitted first by a lead registrant [who] is then acting with the agreement of the other assenting registrants*'. The Claimant also mentioned that Article 3(1) of the Implementing Regulation 2016/9 reaffirms this requirement.⁸
11. On 22 March 2018, the Claimant reminded the Other Party that they needed to register the substance as a member and that the lead registrant should provide all the necessary information. They also informed that, since there had been no answer after several communications asking for the substance identity profile and the Letter of Access, they would submit a data-sharing dispute to ECHA on 3 April, unless the Other Party would provide the requested information.⁹
12. On 6 April 2018, the Claimant submitted a claim under Article 30 of the REACH Regulation concerning the failure to reach an agreement on the access to the joint submission and the sharing of information with the Other Party (for a tonnage band of [REDACTED]).

C. Assessment

13. As explained in section A., ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B.
14. In order to make every effort to reach an agreement, Article 2(2) of the Implementing Regulation 2016/9 requires that upon request, the existing registrant shall provide the itemisation of costs to the potential registrant without undue delay. The Claimant requested the Letter of Access on 8 June 2017 and sent reminders on 24 July 2017, 27 February 2018 and 22 March 2018. The Other Party did not provide this document to the Claimant. Therefore, the Other Party did not make every effort to reach an agreement.
15. Moreover, making every effort to reach an agreement means that an existing registrant also needs to address other requests by a potential registrant.
16. ECHA notes that the Other Party made an effort to reach an agreement, when they provided the Claimant with information regarding the substance identity profile, the reimbursement scheme and the costs to join the joint submission for the tonnage bands [REDACTED] and [REDACTED] on 29 May 2017. The Other Party however ceased to reply to the Claimant's requests after this email.
17. In total, the Claimant contacted the Other Party four times without receiving a reply. In those messages, the Claimant requested three times the Letter of Access, twice the substance identity profile document and once the invoice in order to progress with their registration, but the Other Party did not provide any answer. Moreover, despite of not receiving a reply from the Other Party since May 2017, the Claimant kept on sending reminders to the Other Party

⁶ Claimant; 8 April 2018.

⁷ Claimant; 24 July 2017.

⁸ Claimant; 27 February 2018.

⁹ Claimant; 22 March 2018.

until March 2018.

18. The Claimant communicated clearly their requests concerning the Letter of Access, the substance identity profile document and the invoice. They also informed the Other Party about their urgency to register and emphasised the lead registrant's obligations to share data according to the REACH Regulation. The dispute was lodged to ECHA on 6 April 2018, which is almost ten months after the first reminder was sent to the Other Party on 8 June 2017. The Claimant made effort to reach an agreement by providing the Other Party a generous amount of time to reply to the Claimant's emails before they lodged the dispute. Because the Claimant did not receive a reply to their requests and the reminders, they could not have negotiated further and made any more effort to reach an agreement with the Other Party. In light of the above, the Claimant made every effort to reach an agreement.
19. Therefore, because the Other Party did not provide the Letter of Access to the Claimant and as the Other Party did not address the requests made by the Claimant despite of several reminders, the Other Party failed to make every effort to reach an agreement.

D. Conclusion

20. The Claimant made every effort to reach an agreement on the access to the joint submission and the sharing of information, whereas the Other Party failed to make such effort.
21. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies specified in Annex [REDACTED]

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