

Helsinki, 13 August 2018



Decision number: Dispute reference number: Name of the substance (the 'Substance'): EC number of the Substance:



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.

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

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.

³ Available at https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-



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/quest/regulations/appeals.

Yours sincerely,

Christel Schilliger-Musset4

Director of Registration

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 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 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 12 June 2018. The Other Party was requested to submit evidence on 20 June 2018 and reminded thereof on 5 July 2018. The Other Party did not provide any evidence to ECHA.
- 6. On 5 April 2018, the Claimant contacted the Other Party by sending an email to the email address that the Other Party had provided as contact information to the pre-SIEF page in REACH-IT. The Claimant asked to receive information on cost of the Letter of Access for joining the joint submission for the Substance in tonnage bands
- 7. On 12 April 2018, the Claimant sent a reminder of the previous message.
- 8. On 14 May 2018, the Claimant sent an additional reminder, this time to a different email address, and informed that in case the Other Party did not reply, the Claimant would file a dispute with ECHA.
- 9. On 1 June 2018, the Claimant sent another reminder and asked, firstly, for the price of the Letter of Access for tonnage bands _______, and, secondly, for the cost of the token 'to access the [j]oint [s]ubmission (as an opt-out registrant)'. The Claimant asked the Other Party to reply by 7 June 2018 or they would file a dispute with ECHA.
- 10. On 12 June 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. As the Other Party did not reply to any of the Claimant's emails, it did not make every effort to reach an agreement. The Claimant made every effort to reach an agreement as they tried to start the negotiations by contacting the Other Party four times, even using alternative email addresses. In all their communications, they made a clear request to join the joint submission and asked for the price of the Letter of Access. After not receiving a reply, the Claimant also asked for the price of the token. However, without a reply from the Other Party, it was not possible to progress in the negotiations. Therefore, it was not possible for the Claimant to make any further efforts to find an agreement with the Other Party. In light of the above, and considering the filing of the dispute with ECHA as the last resort in the negotiations, the Claimant made every effort to reach an agreement.

D. Conclusion

- 13. 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 do so.
- 14. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies specified in Annex II.

-

⁵ The Claimant, 5 April 2018, 12 April 2018, 14 May 2018, 1 June 2018.

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