

Helsinki, 10 December 2018



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

A. Decision

ECHA does not grant you the permission to refer to the information you requested from the Existing Registrant of the Substance.

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

The reasons for this decision are set out in Annex I.

¹ Acting as a third party representative pursuant to Article 4 of Regulation (EC) No 1907/2006. ECHA notes that where a potential registrant has made use of a third party representative according to Article 4 of the Regulation, the rights and obligations under REACH solely apply to the potential registrant.

² 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.

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 will be published in an anonymised version on ECHA's website⁴.

B. Recommendation

Under Articles 30 and 11 of the REACH Regulation and the Commission Implementing Regulation, the parties must still make every effort to reach an agreement on the sharing of the information and costs related to the access to the joint submission. Therefore, the parties should continue to negotiate in order to reach an agreement that will be satisfactory for both parties. If the future negotiations fail, the Claimant is free to submit another claim, covering the efforts that occurred after the submission date of the dispute claim that lead to the present decision (i.e. 17 October 2018).

Advice and further observations are provided in Annex II.

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-Musset⁵

Director of Registration

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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 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

- 4. This summary of facts is based on the documentary evidence submitted by the Claimant on 17 October 2018 and by the Other Party on 8 November 2018.
- 5. When a company does a pre-registration, they obtain access to the pre-SIEF webpage on REACH-IT, which contains contact details of the potential registrants for the sake of data-sharing. In this case, the pre-SIEF page contains a functional email address and phone number provided by the SIEF formation facilitator and functional email address and a phone number from the lead registrant. With a further search, the Claimant could find an e-mail address referring to an individual in the Other Party and a different phone number.
- 6. On 17 May 2018, the Claimant contacted by email the Other Party via the email carrying an individual name mentioned above. They asked for the Letter of Access ('LoA') cost in the tonnage band . The Claimant sent reminders on 27 July 2018 and 17 August 2018. On 9 October 2018, the Claimant sent another reminder and requested a reply from the Other Party before 16 October 2018, or '[they] would [submit] a dispute to ECHA.'
- 7. According to the evidence, the Claimant never tried to use the other email addresses or phone numbers available on REACH-IT to contact the SIEF formation facilitator or the Other Party.
- 8. On 17 October 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.



9. On 8 November 2018, the Other Party submitted evidence to ECHA indicating that the email address used by the Claimant was no longer in use, as the Other Party's REACH registration contact person had changed. They had therefore 'not retrieved [...] any direct request from [the Claimant] to register, or access the data relating to [the Substance]'.

C. Assessment

- 10. As explained in section A., ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B.
- 11. ECHA notes that the Claimant made some efforts to begin the negotiations by contacting the Other Party by email four times between May and October 2018, to receive information on the LoA cost, therefore giving the Other Party time to reply to their requests. Without a reply to their emails, the Claimant decided to file a data-sharing dispute with ECHA.
- 12. Making every effort means doing what a reasonable person willing to find an agreement would do. When the Claimant did not receive any reply from the Other Party on the personal email address, every effort means trying other contact details that have been communicated for the purpose of data-sharing. In this case, a reasonable person wanting to reach an agreement on data-sharing would try using the email addresses and the phone numbers available on REACH-IT to contact the Other Party.
- 13. Therefore, the Claimant did not exhaust all possible means of contact before submitting a dispute to ECHA, in order to receive access to the joint submission and permission to refer to the data. A data-sharing dispute is a last resort measure to be used when all efforts are exhausted. By contacting ECHA without exhausting the available means of contact in REACH-IT, the Claimant had not made every effort.

D. Conclusion

- 14. The Claimant did not make every effort to reach an agreement on the sharing of information.
- 15. Therefore, ECHA does not grant the Claimant permission to refer to the studies.

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⁶ The Claimant, 17 May 2018, 27 July 2018, 17 August 2018, 9 October 2018.



Annex II: ADVICE AND FURTHER OBSERVATIONS7

- Concerning the evidence submitted by the Other Party, ECHA reminds that the obligation to share information as defined in the REACH Regulation remains even though the lead registrant is planning to cease manufacturing the substance in the future.
- The Board of Appeal of ECHA stated in its decision A-005-2012, paragraph 34, that 'it is the responsibility of every REACH-IT account holder to update the information concerning its user account details'.8 Therefore, the Other Party should keep their email contact details for the Joint Submission in REACH-IT up-to-date as a data owner.
- The Parties should continue the negotiations aiming to reach an agreement on the access to the joint submission and on the sharing of information.

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⁷ Please note that this section does not contain elements that ECHA took into consideration in its assessment of the parties' efforts in their negotiations. ECHA's assessment of the dispute is set out only in the section 'C. Assessment' of Annex I. The Annex II 'Advice and Further Observations' aims only at providing further advice and information that can be helpful for the parties in the future of their discussions on data sharing and joint submission obligations.

⁸ Decision of the Board of Appeal of the European Chemicals Agency, A-005-2012, 27 February 2013, available at: https://echa.europa.eu/documents/10162/aeff543d-b86a-4dbf-8205-ef884947831a

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