

[REDACTED]
Helsinki, 30 July 2018

The Claimant

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

Copy to:

The Other Party

[REDACTED]
[REDACTED]
[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 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/guest/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 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 implementing a clear and comprehensible cost itemisation and justification as set out in Article 2 of the Implementing Regulation 2016/9. A potential registrant has the right to receive, without undue delay, said itemisation that links cost items with data requirements and provides a justification for each cost item. The information provided must be detailed enough to allow the potential registrant to assess the specific need of the studies, their individual costs and the relevance of administrative costs. This information is essential to enable a potential registrant to assess whether the requested compensation for access to data and to the joint submission is fair, transparent and non-discriminatory as required by REACH and the Implementing Regulation 2016/9.

Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 5 May 2018 and by the Other Party on 22 May 2018.
6. On 11 January 2017, the Claimant sent a message to the pre-SIEF members for the Substance and indicated their intention to register in the tonnage band [REDACTED]. The Claimant also informed of their intention to '*participate actively in the preparation of the dossier*' and inquired whether any pre-SIEF member volunteered for the Lead Registrant role. Further, the Claimant proposed criteria for evaluating substance sameness and invited other members to share their available data on the Substance. The Claimant asked for answers and data contributions from the other pre-SIEF members by 10 February 2017.
7. On 17 January 2017, the Other Party sent a message to the pre-SIEF members stating that they had been elected the Lead Registrant in [REDACTED]. The Other Party informed that they had '*finished all necessary tests for a registration in the tonnage band [REDACTED], and that the joint-dossier [would] be submitted in the 1 Quarter 2017*'.

8. On 8 February 2018, the Claimant sent another message to the pre-SIEF members, including the Other Party, and indicated that the Other Party had not replied or given an update on the status of the dossier after 17 January 2017. The Claimant also referred to emails from 18 December 2017 and 7 February 2018, sent to the pre-SIEF members by a third party, in which the Other Party was asked to provide an update on the registration and an indicative Letter of Access ('LoA') cost by 13 February 2018.
9. On 13 April 2018, the Claimant contacted the Other Party reiterating that there had been no reply from them since 17 January 2017 and the status of the dossier was therefore unknown. The Claimant requested information on the Other Party's intention to continue as the Lead Registrant, the status of the registration and a LoA cost calculation for the tonnage band [REDACTED] by 27 April 2018. Otherwise, the Claimant would '*need to contact ECHA for immediate support*'. On the same day, the Other Party replied that they had finished the registration for the Substance and started the LoA price calculation, for which they '[were] *still waiting for the test costs from a third party*'. The Other Party indicated that the Claimant would receive an update in the following week.⁵
10. On 5 May 2018, the Claimant submitted the present dispute 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. 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 an itemisation of costs to the potential registrant without undue delay. Any delays need to be justified, and a delay cannot in any case be justified if it results in obstructing potential registrants that have contacted the lead registrant in a timely manner from registering. Information on costs is the basis for data-sharing negotiations and crucial for the potential registrant to assess whether the requested compensation is fair, transparent and non-discriminatory.
13. The communication between the Claimant and the Other Party was limited to a few messages, often addressed to other pre-SIEF members as well. After January 2017 there was a break of one year in the negotiations, during which the Other Party did not give an update to the pre-SIEF members on the registration dossier's status, and the Claimant did not send any reminders to the Other Party.
14. On 8 February 2018, the Claimant referred to a third party communication from 7 February 2018, in which the Other Party was asked to provide an update on the registration and an indicative LoA cost. Later, the Claimant requested a LoA cost offer and a breakdown of said costs on 13 April 2018.⁶ On the same day, the Other Party agreed to provide the information in the following week.⁷ However, after three weeks the Claimant had not received any of the requested information. This delay was not justified by the Other Party.
15. Providing a price offer and a cost breakdown for accessing the joint submission is a starting point of the negotiations for the parties. The requested information should be provided to the Claimant without undue delay. Making every effort in the negotiations requires the parties to negotiate in a constructive and timely manner. The Other Party need sufficient time to gather the requested information and the Claimant can expect to receive such information without

⁵ The Other Party, 13 April 2018.

⁶ The Claimant, 13 April 2018.

⁷ The Other Party, 13 April 2018.

undue delay. By not providing the requested information, the Other Party put the Claimant in a situation, where they could not conduct negotiations on possible data-sharing and access to the joint submission. Therefore, by not communicating to the Claimant the LoA costs and not providing an itemisation of the study and administrative costs without undue delay, the Other Party failed to make every effort to reach an agreement on data sharing.

16. Consequently, by not addressing the Claimant's requests and not conducting meaningful negotiations, the Other Party blocked the Claimant from reaching an agreement on data-sharing and access to the joint submission, and thereby failed to comply with the obligation to make every effort to reach an agreement. On the other hand, in light of the approaching REACH registration deadline of 31 May 2018 and taking into consideration the insufficient communication and lack of replies from the Other Party, the Claimant made more effort in the negotiations and filed the dispute claim as a measure of last resort.

D. Conclusion

17. Based on the above, ECHA concludes that the Claimant made every effort to reach an agreement on data-sharing and access to the joint submission, whereas the Other Party failed to do so.
18. 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."