

[REDACTED]
Helsinki, 19 September 2018

The Claimant

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

Represented by

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

Copy to:
The Other Party

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

Represented by

[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

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.

(‘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.

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

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 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. Part of making every effort means that upon request the existing registrant must, according to Article 2(2) of the Implementing Regulation 2016/9, provide potential registrants with an itemisation of all relevant costs and proof of such costs, without undue delay. Providing this information without undue delay is necessary to establish a solid basis and starting point for the cost-sharing discussions between the parties. Through this information, a potential registrant is able to assess the requested costs on an objective basis. No dossier-related cost can be properly understood and, if necessary, challenged, if the above information is not supplied by the existing registrant.
4. Making every effort also 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.

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 11 July 2018 and by the Other Party on 10 August 2018.
6. On 7 May 2018, the Claimant contacted the Other Party to request the Letter of Access (LoA) in the tonnage range of [REDACTED], and to inquire about the costs incurred and ask whether a Chemical Safety Report was available.⁵
7. On 9 May 2018, the Other Party sent the Claimant the substance information exchange forum (SIEF) and LoA agreements, and asked them to '*[p]lease complete, sign, and scan the documents and send them back*'.
8. On 16 May 2018, the Claimant queried the LoA cost, as the price for [REDACTED] and [REDACTED]

⁵ Claimant; 7 May 2018 (emails sent at 15:25 and 16:11).

██████████ were the same, at ██████████ euros. They asked the Other Party to justify this *'since the LoA for those two tonnage ranges cover different references.'* The Claimant noted that *'[i]n the tonnage range of ██████████ the LoA would cover reference to the technical dossier and the ██████████ and in the tonnage range of ██████████ the LoA would cover reference to the technical dossier only.'* With regard to their request for a LoA for ██████████, they wrote that *'the costs would be as high as for a tonnage range of ██████████, which seems at least unusual.'*

9. On 17 May 2018, the Other Party replied that *'[t]he LoA price was set up based on the total dossier cost and not for profit principle and served to cover budget needs for maintaining registration dossier.'* They said that when the LoA cost was calculated, *'there was no detailed knowledge about the amount of potential LoA buyers for various tonnages that is why a flat fee for both tonnage bands was set.'* The Claimant replied the same day, stating that *'[r]egarding the costs, [the Claimant] would like to point out that [the Claimant's] [...] tonnage range is ██████████. Accordingly, the data required for the registration for this tonnage range is ██████████ than for ██████████ or even ██████████.'* With *'reference to the competition law,'* they requested a *'reduced fee for the LoA (██████████) which takes the ██████████ into account.'*
10. On 23 May 2018, the Other Party stated that a *'[n]umber of other companies registered ██████████ for ██████████ and [the Other Party] never [...] received such request which means that those companies paid the fee as it stands in [the] LoA Agreement.'* The Other Party noted that they had *'never privileged any company by applying special rules or special fees since those were agreed and set by the consortium many years ago.'*
11. On 30 May 2018, the Claimant requested the Other Party to *'explain to [the Claimant] how the costs for the LOA are determined in the tonnage ranges ██████████ and ██████████y?'* They also asked the Other Party to *'explain why the same fee is charged for both tonnage ranges, although different registration requirements are necessary and different information is provided (██████████/technical dossier)?'*
12. On 1 June 2018, the Other Party stated that *'[g]iven the total dossier cost, the consortium had decided that despite the different requirements necessary for the tonnage range, the data required had to be first developed and paid for and the consortium considered appropriate setting one fee for the tonnages ██████████.'*
13. On 14 June 2018, the Claimant asked for explanations as to how the data costs and tonnage band costs were calculated. They quoted REACH and ECHA's guidance on data-sharing regarding registrants being required to pay only for the costs for information that they actually required, and said that *'[i]t would be helpful if [the Other Party] could provide [the Claimant] with a transparent list of the expenses contributing to the costs of the LoA of the various tonnage ranges.'* They stated that they would be forced to submit a data-sharing dispute with ECHA if they did not receive *'the requested information on the cost breakdown, or only in inadequate form.'*
14. On 9 July 2018, the Claimant, noting that they had not received a reply to the previous email, requested confirmation that the Other Party had received it.
15. On 10 July 2018, the Other Party confirmed receipt of the email of 14 June. They said that they were finalising *'the cost-sharing calculation which should be available within the next few weeks.'*
16. On 11 July 2018, the Claimant informed Other Party that they would be filing a dispute claim with ECHA, as *'[w]aiting for an agreement create[d] a not inconsiderable economic disadvantage.'* They noted that they were still open to negotiations, but they felt required to file the dispute as they had had *'only inaccurate information as to when [the Claimant would] receive an overview of the costs, let alone the prospect of an agreement.'* The same

day, 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 for the tonnage band [REDACTED].

C. Assessment

17. As explained in section A., ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B.
18. At the beginning of communications with the Other Party, on 7 May 2018, the Claimant immediately inquired about the costs incurred in co-registering. The Other Party responded in a timely manner to the Claimant's messages by sending the SIEF and LoA agreements on 9 May. However, when the Claimant, on 16 May 2018, asked for explanations regarding the lack of price differentiation between tonnage ranges, the Other Party did not address these concrete points and questions raised by the Claimant. By not addressing the questions asked by the Claimant and by not providing the information asked for, the Other Party failed to progress the negotiations between the parties, thereby failing to comply with Article 30(1) of the REACH Regulation and Article 4(1) of the Implementing Regulation.
19. In addition to seeking clarification regarding the flat fee, the Claimant explicitly requested '*information on the cost breakdown*'⁶. As the LoA cost is calculated by the Other Party, it is their responsibility to show the Claimant how they prepared the LoA cost via a cost breakdown and their cost-sharing model, even if, as mentioned by the Other Party, other potential registrants had simply '*paid the fee as it stands in LoA Agreement*'.⁷ Without receiving such information from the Other Party, the Claimant was unable to understand the basis of the requested LoA price, such as study costs per endpoint or administrative costs. Consequently, they could not assess whether the LoA cost they were being asked to pay was, indeed, fair. This meant that the Claimant was unable to begin any substantive negotiations. As the Other Party did not provide the information required to assist the Claimant to negotiate, they failed to comply with their obligation to provide an itemisation of costs without undue delay, as required under Article 2(2) of the Implementing Regulation 2016/9.
20. The lack of provision of a cost-sharing model by the Other Party also meant that the Claimant was unable to ascertain whether what they were being asked to pay for was fair and non-discriminatory, or that the requested LoA cost was for only the data required to fulfil the information requirements needed for their tonnage band. The absence of any documentation of the cost-sharing model or how it was devised is another example of the Other Party failing to fulfil their obligation to negotiate in a fair, transparent and non-discriminatory manner.

D. Conclusion

21. Based on the above, ECHA concludes that the Claimant made every effort to progress the data sharing negotiations by clearly stating their concerns, challenging why they were being asked to pay a flat fee for tonnage bands [REDACTED] when their desired tonnage band was [REDACTED], and by requesting a cost breakdown in an effort to understand how the LoA cost was calculated, all in an attempt to move the negotiations forward.
22. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies specified in Annex II.

⁶ Claimant; 14 June 2018.

⁷ Other Party; 23 May 2018.

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