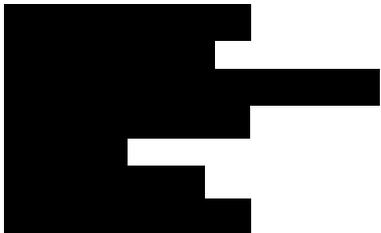



Helsinki, 24 October 2018

The Claimant



Copy to:

The Other Party



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 does not grant you the permission to refer to the information you requested from the Existing Registrant of the Substance, nor 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.

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.

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

B. Recommendation

Under Articles 30(3) 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, that is, after 07 August 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-Musset⁴

Director of Registration

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.



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.

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 07 August 2018 and by the Other Party on 29 August 2018.⁵
6. On 21 February 2018, the Claimant initiated the data sharing negotiations with making a request for the LoA price of the full registration of the substance.⁶
7. On 1 March 2018, the Other Party replied to the request by asking additional clarification regarding the tonnage band.⁷
8. On the same date, 1 March 2018, the Claimant stated that they are interested in registration  t/a.⁸
9. On 2 March 2018, the Other Party contacted the Claimant to identify if they intend to register as intermediate or full member. The Other Party advised the Claimant to get in touch with a third party, who initially registered the substance as intermediate as a part of a group of  substances. The Other Party explained the cost model as '*[t]he LoA price situation is certainly complicated and needs some explanation*'. The Other Party emphasized that in order for the Claimant to become a member of the full registration, the Claimant needs to purchase two

⁵ The negotiations were conducted mainly in 

⁶ Claimant; 21 February 2018

⁷ Other Party; 1 March 2018

⁸ Claimant; 1 March 2018

separate LoAs. The first step for the Claimant would be to contact the third party, which is the registrant of the intermediate dossier and in addition to this to purchase a LoA from the Other Party and one study from a fourth party. The Other Party provided the prices for the LoA for the tonnage bands [REDACTED] t/a and [REDACTED] t/a. The Other Party informed that the provided prices did not include the costs of the studies, which were owned by the other companies. The Other Party provided the contact details of the other companies and informed that the studies should be requested and paid directly to the companies in question. The Other Party provided information on the substance identity profile (SIP).⁹

10. On 5 March 2018, the Claimant asked for clarification of the costs and pointed out that there are already [REDACTED] existing registrants in the joint submission and they could not *'understand'* how the price could be *'so high'* despite this fact.¹⁰
11. On 7 March 2018, the Other Party provided clarifications on the price of the registration and the fact that the group of [REDACTED] substances, of which the disputed substance is part, was registered initially as intermediate. The full registration done by the Other Party was for [REDACTED]. The Other Party provided the generic sum of the total costs for the studies and for the administrative costs of the full registration and explained that due to [REDACTED] there was a need for additional studies. In addition, the Other Party accounted also for other possible costs related to further studies required by ECHA. The Other Party assured that the LoA costs are calculated in proportion to the number of registrants. The Other Party explained that the price will be recalculated after the registration deadline, taking into consideration the actual amount of registrants and any additional study. Finally, the Other Party recommended to the Claimant to contact the registrant of the intermediate dossier. The Other Party explained again that the full registration *'can only be carried out'* once the Claimant has access to the data of the intermediate dossier.¹¹
12. On 25 June 2018, the Claimant requested the recalculated price of the LoA after the registration deadline had passed.¹²
13. On 4 July 2018, the Other Party replied that after the registration deadline, they are facing high numbers of registrations to be recalculated and *'unfortunately'* they are not able to give a time estimation for the recalculated price of the LoA. However, the Other Party proposed to the Claimant to buy the LoA with the current price. The Other Party assured the Claimant that they will be reimbursed, in case of a surplus, after the recalculations have been finalised.¹³
14. On 25 July 2018, the Claimant stated that they *'consider the long time'* needed by the Other Party for the recalculation as *'discriminatory'*. They added, that they *'do not consider the high, non-transparent prices to be fair'*. The Claimant asked the Other Party to *'reconsider'* their price and to provide them *'timely'* with a new offer.¹⁴
15. On 27 July 2018, the Other Party stated that they *'cannot understand'* the Claimant's statement because the prices have been presented in details earlier in the negotiations. The Other Party provided a pdf document which showed the total costs of the administrative expenses and studies for the tonnage band [REDACTED] t/a and [REDACTED] t/a. The Other Party informed that there is *'no legal deadline'* for the recalculations of the LoA after the registration deadline;

⁹ Other Party; 2 March 2018.

¹⁰ Claimant; 5 March 2018.

¹¹ Other Party; 7 March 2018.

¹² Claimant; 25 June 2018.

¹³ Other Party; 2 July 2018.

¹⁴ Claimant; 25 July 2018.

however, they plan to do this in due time. In addition, the Other Party informed that they *'cannot provide more accurate time estimation'*. The Other Party assured again the Claimant that in the event of a surplus they will be reimbursed after the recalculation takes place. The Other Party emphasized again the fact that the Claimant should contact first the initial registrant of the intermediate dossier.¹⁵

16. On 6 August 2018, the Claimant informed the Other Party that they are *'forced'* to submit a dispute to ECHA.¹⁶
17. On 7 August 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.

C. Assessment

18. As explained in section A., ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B. Making every effort means that the parties have exhausted all resources during their negotiation process. Parties in data-sharing negotiations should clearly explain their position and the questions they have, challenge the points they disagree with and assess the justification given in turn. In addition, sharing of costs needs to be fair, transparent and non-discriminatory. If a party does not understand an offer or considers it too high, it should request further clarification indicating on which point of a given calculation it disagrees.
19. The Other Party provided price indications for the different tonnage bands already in the beginning of the negotiations¹⁷. The prices of the full registration for the tonnage bands [REDACTED] t/a and [REDACTED] t/a were presented again by the Other Party just before the Claimant launched the dispute¹⁸. The Claimant pointed out during the negotiations that they *'do not understand'* the high amount of the costs¹⁹. The Other Party provided an explanation for the price but this was not challenged by the Claimant. More than three months later, after the registration deadline had passed, the Claimant contacted the Other Party again and asked for the recalculation of the price. The Other Party indicated they cannot provide the recalculated price yet and that it would be available only later, however, the Claimant could register with the current price. The Claimant argued that the provided *'high'* prices were *'unfair'* and requested therefore the Other Party to *'reconsider'* their price and to provide them *'timely'* with a new offer²⁰. In reply, the Other Party informed that there is *'no legal deadline'* for the recalculations of the LoA after the registration deadline; however, they plan to do this in due time²¹. The Claimant did not continue the negotiations but instead filed a dispute against the Other Party shortly after receiving the information about the recalculation of the prices.
20. ECHA notes that the Claimant has the right to request and receive a cost breakdown as well as to ask for more information if they consider the received cost breakdown not enough detailed and informative or they do not understand the costs. However, the Claimant never requested a detailed cost breakdown. In order to make every effort the Claimant should have

¹⁵ Other Party; 27 July 2018.

¹⁶ Claimant, 6 August 2018.

¹⁷ Other Party; 2 March 2018.

¹⁸ Other Party; 27 July 2018.

¹⁹ Claimant; 5 March 2018.

²⁰ Claimant; 25 July 2018.

²¹ Other Party; 27 July 2018.

asked for a more detailed cost breakdown, or asked further information related to the costs provided by the Other Party, or challenged objectively the proposed prices. In addition, the Claimant could have suggested an alternative price explaining why the proposed pricing would be fair. During the negotiations, the Claimant did not challenge the pricing on the basis of the information provided by the Other Party. Instead of pursuing a constructive approach to progress the negotiations, the Claimant only indicated they consider the price high without providing justification nor asking for more detailed information to better understand the price.

21. In addition, the Other Party frequently informed the Claimant about the fact that in order to become a member of the full registration, the Claimant needs to get access to the data owned by the registrant of the intermediate dossier first. The Claimant was informed about this prerequisite from the beginning of the negotiations. The Claimant never mentioned if they have gotten in touch with the registrant of the intermediate dossier and therefore the Other Party could not know if the requirement for getting access to the full joint registration LoA was fulfilled. The Claimant could have made additional efforts to address this point and to clarify whether they have followed-up on the Other Party's advice.
22. Further to this, ECHA observes that based on Claimant's actions during the negotiations there was no indication of urgency from the Claimant's side and therefore it is not understandable why the Claimant would file a dispute shortly after re-starting the negotiations. The Claimant could have explained the urgency to register and could have further negotiated the current offer of the Other Party.
23. On the other hand, the Other Party could have made more efforts to reach an agreement by providing an estimate for the reimbursement scheme and a concrete reimbursement mechanism. Even though the Other Party provided justification regarding the delay of the recalculation of the registration price, as a sign of good will and cooperation consent, they could have indicated by when they expected the recalculation to take place.
24. Based on the above, the Claimant could have asked for a detailed cost breakdown, challenged objectively the proposed prices and/or suggested an alternative price, asked more details on the reimbursement mechanism, contacted the lead registrant of the intermediate dossier, and explained their urgency to register. On the other hand, the Other Party could have made more effort by providing estimates for the reimbursement scheme and a concrete reimbursement mechanism. Nevertheless, the Other Party was proactive during the negotiations in replying timely and providing the clarifications requested by the Claimant. Therefore, ECHA notes that in the balance of efforts the Other Party made more efforts to reach an agreement.

D. Conclusion

25. Based on the above, ECHA concludes that by not exhausting all efforts, the Claimant did not make every effort to reach an agreement on data sharing and access to the joint submission in a fair, transparent and non-discriminatory way.
26. Consequently, ECHA has decided not to grant the Claimant the permission to refer to the information they requested from the Other Party and not to grant the Claimant access to the Joint Submission.

Annex II: ADVICE AND FURTHER OBSERVATIONS²²

The Parties should continue the negotiations aiming to reach an agreement on the access to the joint submission and on the sharing of information.

ECHA underlines that both parties should make every effort to reach an agreement on the sharing of the information and of their related costs. ECHA notes that some items in the present negotiations have not been clarified and the outcome of the present decision mainly results from the fact that the Claimant and the Other Party did not exhaust all efforts. ECHA encourages both parties to take into consideration the remarks given below to facilitate the negotiations and to reach an agreement on data sharing:

It is also crucial that existing registrants allow potential registrants to understand their cost-sharing mechanism, in order to facilitate further discussions towards an agreement (Article 2 of the Implementing Regulation 2016/9). In this regard, ECHA understands, e.g., that the Claimant did not have a clear picture of the studies costs and the administrative costs and the model used for the sharing and allocation of costs among substances and among registrants. On request, this may need to be clarified by the Other Party in order to allow the Claimant to fully understand the cost-sharing model and be in a position to assess it and negotiate.

The Agency also points out that a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would. Accordingly, ECHA strongly encourages the parties to continue their efforts to reach an adequate agreement that will be satisfactory for both parties.

²² 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.

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