[redacted]

Helsinki, 18 October 2018

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

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

[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.

[redacted]

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

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-Musset[4]

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.

[redacted]

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, making every effort means providing potential registrants with the clear and comprehensible data-sharing agreement, which shall include, *inter alia*, the itemisation for all relevant costs and a cost-sharing model with a reimbursement mechanism as set in Article 2 of the Implementing Regulation 2016/9. The itemisation for all relevant costs shall be provided upon request without undue delay. When the itemisation and justification of costs are provided, potential registrants are able to assess whether the requested compensation is fair, transparent and non-discriminatory. 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 other company in a timely manner from registering.

[redacted]

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 30 May 2018 and by the Other Party on 22 June 2018.

6. On 4 July 2016, the Claimant communicated to the SIEF members their intention to become a lead registrant as Only Representative for a third party and prepare the registration dossier in the tonnage band [redacted]. They requested the SIEF members to express the potential objections by 18 July 2016; otherwise, the Claimant would assume that their lead registrant's [LR] role was accepted.

7. On 27 July 2016, with reference to the Claimant's email of 4 July 2016, the Other Party clarified that they *'ha[d] already […] LR status […] for this product and ha[d] already commenced [their] initial preparations to have this product registered in a timely fashion'*. They stated that *'the matter of LR is now closed and we find this additional communication by [the Claimant] both unhelpful and confusing'* and they hoped that the Claimant *'[would] now act in the best interest of all SIEF members and acknowledge that [the Other Party was] the appointed LR by communication through the SIEF (copy list) before the end of July 2016 to prevent any further confusion'*.

8. On 30 August 2016, the Other Party requested the SIEF members to indicate whether they had any existing data for the Substance, informing that if no existing data was available within the SIEF, the Other Party would perform a data gap analysis.

9. On 22 November 2017, the Claimant informed the Other Party of their intention to register the Substance in the tonnage band [redacted] on behalf of their non-EU client and requested the Other Party's *'feedback on below points'*: (i) tonnage band of the lead dossier; (ii) Substance Identity Profile (SIP); (iii) *'Summary on current status of the lead dossier preparation and the timeline for submission'; (iv) 'Indicative LoA [Letter of Access] cost for [redacted]'; (v) 'by when [they] can expect to receive SIEF agreement and LoA to submit co-registrant dossier'*.

10. On 12 December 2017, the Other Party replied accordingly: (i) they were preparing the dossier in the tonnage band [redacted]; (ii) the SIP was attached; (iii) [redacted] and [redacted] test were carried out and the lead dossier was scheduled to be completed by 28 March 2018; (iv) they *'haven't estimated the LoA cost at this stage'*; (v) the SIEF agreement and LoA would be provided in February 2018.

11. On 11 January 2018, the Claimant requested the Other Party to provide *'regular updates'* on the following points: (i) whether the Other Party would be able to register by March 2018; (ii) whether the Other Party would submit the dossier in [redacted]; (iii) whether the LoA and the SIEF agreement would be provided by February 2018; (iv) and what would be the indicative LoA cost in the tonnage band [redacted] and [redacted]. The Claimant emphasised that *'as [the Other Party would] be following current data sharing guidelines on LoA cost calculation, [the Claimant] also request[ed] […] the itemised LoA as per "new" data sharing implementing Regulation (EU) 2016/9'*. The Claimant asked the Other Party to reply by 18 January 2018.

12. On 6 February 2018, the Other Party confirmed that they were preparing the dossier in the tonnage band [redacted] and planned to submit it by 31 March 2018. Regarding the LoA cost, the Other Party replied that they *'ha[d not] summed up total cost so [they were] unable to provide the estimation for the time being'*, but cost calculation would be completed by the end of March. The Other Party confirmed that they *'[were] aware of the new data sharing obligations and will do [their] best to follow that guidelines'*. On 7 March 2018, the Other Party repeated that the dossier would be submitted by the end of March. They requested the Claimant to sign the *'declaration of approval'* and stated that they were *'following strictly to*

[redacted]

the new data sharing regulation and will be provide the LoA accordingly once the dossier is ready'.

13. On 29 March 2018, the Other Party acknowledged that they *'could not provide [the Claimant with] the LoA cost on the promised deadline'*. They stated that *'[t]he dossiers have been completed but [they were] still reviewing the cost for this project, and calculating cost for different tonnage bands'* and they would contact the Claimant *'around mid April'*.

14. On 16 April 2018, the Claimant indicated that they wished to register the Substance in the tonnage band [redacted] and expressed their concerns that according to ECHA dissemination portal the lead dossier for the substances of their interest, including the Substance in question, had not yet been submitted by the Other Party. The Claimant requested to be provided with the LoA costs and the SIEF agreement *'along with a precise and accurate timetable when co-registrants [could] join the Joint Submission and submit their co-registrations by end of business day tomorrow (17.4.2018)'*. Further, they stated that if they did not receive the LoA costs and other requested information, they *'[would be] forced to contact ECHA for dispute lodging/re-electing LR as you are unable to maintain statements as per earlier communications and postponing in providing SIEF members with the information they need despite earlier promises'*. The Other Party replied on the following day that they *'were still working on the LoA costs'* because they *'ha[d not] settled the management fees with some of [their] co-registrants'*, and they would provide the LoA costs by 20 April 2018. They informed the Claimant that they were *'still fixing the TCC [Technical completeness check] problems of the dossiers and therefore the submission was delayed'* and dossiers would be submitted by 22 April.

15. On 20 April 2018, the Other Party provided LoA costs and the cost breakdown for the Substance for tonnage bands [redacted] and [redacted], pointing out that there were [redacted] co-registrants, [redacted]. On 25 April 2018, the Claimant asked for a clarification regarding *'a typo error'* in the indicated LoA costs; the Other Party acknowledged and corrected the typing mistake on 26 April 2018.

16. On 23 May 2018, with reference to the Other Party's email of 26 April 2018, the Claimant inquired as to *'why there [was] effectively no LoA cost difference for [redacted] and [redacted]'* and requested the cost itemisation per each tonnage band separately, as *'it [was] not possible for [them] to differentiate on LoA fee itemization for both the bands'*.

17. The Other Party replied on the same day that the cost itemisation per tonnage would be provided by 24 May 2018. They also explained that there was no significant difference in LoA cost between [redacted] tonnage bands for the reason that *'the new studies were conducted for endpoints required for [redacted]. For endpoints [redacted], the data were collected from published articles, which did not cost much'*.[5]

18. On 24 May 2018, the Claimant requested to be provided with the full itemisation of LoA cost for tonnage bands [redacted] and [redacted], including data itemisation per endpoint, administrative costs and additional data/testing cost based on testing proposals *'by EOD today, 24.05.18'*.

19. The Other Party replied on the same day[6] that they would be able to provide the full itemisation on the following day. They also informed the Claimant that the submission for the Substance had passed the technical completeness check and they had received a registration number.

20. On 25 May 2018, the Other Party provided additional information regarding LoA calculation,

[5] The Other Party; 23 May 2018
[6] The Other Party; 24 May 2018

[redacted]

study costs per endpoint, cost sharing model and management fee in the attachments.

21. On 30 May 2018, the Claimant replied that they were going to file a dispute claim on the grounds that: (i) the cost itemisation was provided on 25 May 2018, and that was *'too late to assess the full quality and reliability of the costs presented considering the registration deadline [was] 31st of May 2018'* ; (ii) the provided study cost itemisation was not detailed enough, in particular, *'the cost item '[redacted]'' […] [was] diproportionate [sic] high compared to that cost at [redacted] as [redacted]'*. They also highlighted that *'the read-across could have been used more extensively to avoid testing costs'* and indicated the studies that in their opinion were unnecessary.

22. On 30 May 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

23. As explained in section A., ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B.

24. ECHA notes that the Claimant actively expressed their wish to obtain a lead registrant's role for joint submission for the Substance in 2016. However, the Other Party insisted on their lead role and reassured the SIEF members that they *'ha[d] already commenced [their] initial preparations to have this product registered in a timely fashion'.*[7]

25. In November 2017, the Claimant informed the Other Party of their intention to register the Substance in the tonnage band [redacted] and inquired about the status of the dossier preparation and the timelines for its submission. They requested the indicative LoA cost and asked the Other Party to indicate the timelines for the provision of the SIEF agreement and LoA. In December 2017, the Other Party provided the SIP and informed the Claimant about the tests performed for the dossier, but was not able to provide any further information about the LoA costs.

26. At this stage, the Other Party could have made an effort to give an LoA cost estimation based on the costs of the studies already performed for the dossier preparation, or expressly indicate the study costs. This information could have served as a starting point for the negotiations between the parties on cost sharing.

27. In their email of 11 January 2018, the Claimant explicitly indicated that they expected the Other Party to pursue ECHA's Guidance on data sharing while calculating the LoA costs, and provide the Claimant with the cost itemisation that would meet the mandatory requirements set in the Implementing Regulation 2016/9. The Other Party acknowledged that request and was aware of the Claimant's expectations regarding the cost itemisation.

28. It should be recalled that the itemisation requirement, in light of Implementing Regulation 2016/9, serves to provide a meaningful basis for discussions on the objective costs of the data and to allow a further assessment whether these costs are sufficiently justified. Therefore, the itemisation of the data and administrative costs is crucial to enable meaningful negotiations in order to reach a fair, transparent and non-discriminatory agreement between co-registrants, and should be done without undue delay.

29. However, in spite of reassuring the Claimant that the dossier would be submitted by the end of March 2018 and that the LoA cost would be communicated then, the Other Party provided the LoA costs and the first cost breakdown only on 20 April 2018.

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[7] The Other Party; 27 July 2016

[redacted]

30. After receiving the cost breakdown, the Claimant considered that it was not sufficient for assessing whether the requested cost compensation was reasonable and shared in a fair and transparent way and therefore had to make an additional request for details on the administrative costs and study costs. Following that request, the Other Party provided the last version of the cost itemisation and details regarding the cost sharing model on 25 May 2018.

31. ECHA notes that the Claimant did not immediately challenge the first cost itemisation received on 20 April 2018. However, the Other Party, who had been Lead Registrant since 2016, took several months to provide this cost itemisation. Therefore, the balance between the parties' efforts remains unchanged.

32. As they were providing the LoA costs and the cost itemisation at a very late stage before the registration deadline, to make every effort, the Other Party should have presented a fully itemised LoA proposal that would allow potential registrants to assess the requested administrative and study cost compensation without asking for additional clarifications or justification of the costs, thus allowing the negotiations to be immediately finalised. The delays in providing the information required are especially relevant in light of the registration deadline of 31 May 2018.

33. Hence, the Other Party did not make every effort to reach an agreement on fair, transparent and non-discriminatory sharing of costs.

D. Conclusion

34. The Other Party did not make every effort in the negotiations and failed to comply with their obligation to come to an agreement by not duly providing the LoA costs and the cost itemisations to the Claimant.

35. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies specified in Annex II.