[redacted]

Helsinki, 9 August 2018

The Claimant

[redacted]

Represented by

[redacted]

Copy to:
The Other Party

[redacted]

Represented by

[redacted]

Decision number: [redacted]
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 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].

[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]

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 website[3].

B. Observations

ECHA reminds both parties that despite the present decision they are still free to reach a voluntary agreement. In particular, ECHA notes that the negotiations on sharing the cost of [redacted] study between the parties were not finalised at the time when the dispute was filed. Neither party had exhausted their efforts on the sharing of the cost of [redacted] study. 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 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.

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.

[redacted]

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 5 April 2018 and by the Other Party on 4 May 2018.

6. Between September and December 2017, the parties communicated on the details of the Substance Identity Profile (SIP) and the Letter of Access (LoA) cost. The Other Party informed the Claimant that the LoA cost in the tonnage band [redacted] was [redacted] €.

7. On 13 December 2017, the Claimant requested '*a cost breakdown for each Annex* [redacted] *and* [redacted] [sic] *study, as well as administration cost for the LoA*'. On 16 January 2018, the Claimant sent a reminder of the request to the Other Party.

8. On 16 January 2018, the Other Party provided a cost itemisation in percentage shares of the total cost. On the next day, 17 January 2018, the Claimant requested '*a table with the specific total EUR amounts per endpoints for Annex* [redacted] *and* [redacted] *the share per co-registrants and the applied REACH-only rebate for each study.*'

9. On 19 February 2018, the Other Party provided a second cost breakdown that divided the costs into various administrative and study costs without Annex-specific endpoint details or information on the cost-sharing principles between co-registrants.

10. On the same day, the Claimant requested that the Other Party follow ECHA guidelines on cost sharing and asked for details on the co-registrants and '*extremely high*' administrative costs categorised under '*Co leader*', '*Consortium management*' and '*Lead Registrant costs*'. The Claimant also challenged sharing [redacted] study costs because it was an Annex [redacted] endpoint.

11. On 5 March 2018, the Other Party answered that there were [redacted] registrants sharing the costs and that the Lead Registrant's administrative costs were due to '*several meetings and travels*'. In addition, the Other Party indicated that '[c]*onsidering that there is a co-leader, an extra cost* [has] *been considered for this consortium management*'. Regarding [redacted] study cost, the Other Party answered that the study in question was selected because it was the only existing study to cover the particular endpoint.

12. On 8 March 2018, the Claimant asked for a more detailed cost-sharing model with an itemisation of administration costs. The Claimant stated that '*It is not clear what the total cost of the lead dossier is, and how each (of the* [redacted] *co-registrant participates in the total cost.*' Further, the Claimant requested the Other Party to '*provide a detailed itemisation and justification of the lead registrant cost, co-leader cost and consortium management cost.*' Finally, the Claimant requested a justification for their contribution to the cost of [redacted] study.

13. On 14 March 2018, the Other Party provided a more detailed cost-sharing table and informed the Claimant that another company was expected to join the joint submission, further decreasing the price.

14. On 16 March 2018, the Claimant refused to share [redacted] study cost, explaining again their standpoint that they do not need [redacted] study to fill the information requirements for their tonnage band. Instead, the Claimant proposed to contribute to the cost of [redacted] study with a rebate for REACH-only use. The Claimant pointed out that they have not received adequate answer regardless of repeatedly addressing their concerns and mentioned filing a dispute with ECHA.

15. On 23 and 27 March 2018, the Other Party indicated that [redacted] study was bought to cover endpoints in both Annexes [redacted] and [redacted] in the registration. The Other Party itemised the administrative costs as salary expenses for two employees as well as travel and

meeting expenses.

16. On 5 April 2018, the Claimant indicated that it did not consider '*the explanation of the administrative cost* […] *to be sufficient to enable* [them] *to assess whether the requested price* [was] *fair, transparent and non-discriminatory.'* Further, the Claimant repeated that it would not participate in [redacted] test, but would instead 'contribute to the testing cost of [redacted] study'.

17. On 5 April 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 data sharing 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. The documentary evidence provided by the parties included negotiations firstly on the data requirements for the Claimant's registration and secondly on the transparency of the Other Party's itemisation of administrative costs.

Study costs

19. In accordance with Article 30(1) of the REACH Regulation, '*the participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way*'. In accordance to Article 4(1) of the Implementing Regulation 2016/9, a registrant is '*required to share costs* […] *to satisfy his registration requirements*' and '*this condition applies also to administrative costs.'*

20. Therefore, upon request, a potential registrant must receive without undue delay a meaningful cost breakdown in relation to the data submitted in the joint submission from the existing registrants. This cost breakdown must link the relevant cost items with the data requirements and provide a justification for each cost item. The cost-breakdown should be elaborated enough to allow the potential registrant to assess the relevance of different cost items and adequacy of the LoA cost.

21. After receiving the second cost breakdown[5] from the Other Party, the Claimant requested a justification for sharing the cost of [redacted] study, as it was an Annex [redacted] endpoint[6]. The Other Party justified the use of the study by indicating firstly that the study was bought to cover [redacted] in order to avoid duplicating animal tests[7] and secondly that the price was similar to [redacted] study[8]. Where higher tier studies are shared by the lower tonnage band registrants, the co-registrants could consider agreeing on a cost sharing mechanism that takes into consideration the following two factors: 1) there is no need for low tonnage band registrants to provide the higher tier studies and 2) the relevant lower tier studies (which is required for lower tonnage bands) does not exist. As an example, the co-registrants could agree on a replacement cost of such non-existing study lower tier study as a fair contribution to the costs of generating the corresponding existing higher tier study. However, the Other Party did not make every effort to take into account the Claimant's lower tonnage band and adjust the cost share accordingly.

22. The Claimant proposed to contribute to [redacted] study [redacted] price to cover the Annex [redacted] endpoint[9]. However, as the Other Party indicated, no such study existed for registration purposes and the Claimant's cost share would have been similar in

[5] The Other Party, 19 February 2018.
[6] The Claimant, 19 February 2018.
[7] The Other Party 5 March 2018
[8] The Other Party 23 March 2018
[9] The Claimant, 16 March 2018.

case such a study had been performed. As per Annex [redacted], [redacted] *study* [redacted] *does not need to be conducted if* […] *a reliable* [redacted] *or* [redacted] *study is available*". Therefore, the Claimant did not make every effort to negotiate on sharing the price of a study needed for their registration.

23. Consequently, ECHA notes that neither party made every effort to reach an agreement on sharing the costs of [redacted] study.

Administrative costs

24. As for the sharing information about the costs, the sharing of administrative costs shall be determined in a fair, transparent and non-discriminatory way and both parties shall make every effort to reach an agreement.

25. In accordance to Article 4(1) of the Implementing Regulation 2019/9, the cost breakdown provided by the Other Party must also include information and justification regarding the administrative costs, including costs related to joining the joint submission. This information must be detailed enough to allow the potential registrant to assess the specific need for each study and its cost and the relevance of the requested administrative costs for the potential registrant's registration.

26. After their initial requests[10], the Claimant requested a cost-sharing information explicitly referencing the principles of the Implementing Regulation 2016/9[11]. The Other Party provided three different cost-sharing calculations, each containing a differing cost itemisation.

27. The first cost-sharing information[12] that the Other Party sent to the Claimant was a pie chart that indicated in percentages the cost-sharing principles for the Letter of Access. The chart included [redacted] study costs, the [redacted] cost, and [redacted] different administrative costs (Lead Registrant costs, Co leader and Consortium management). Some of the values of the chart were not named in the legend. The Claimant questioned the information by asking for '*a table with the specific total EUR amounts per endpoints for Annex* [redacted] *and* [redacted] *the share per co-registrants and the applied REACH-only rebate for each study*'.[13] Based on the Claimant's questions, the provided chart did not allow the Claimant to understand how the administrative costs had incurred and to assess objectively the requested price.

28. The Other Party provided a second cost-sharing table one month after the Claimant's second request[14]. The table indicated [redacted] study costs, the [redacted] cost and [redacted] administrative cost items (Lead Registrant, Co leader, Consortium management, Calculation of LoA cost, Translation services and Admin cost). Whereas this table was more detailed than the pie chart provided at the first place, the provided information again did not either link the cost items with the data requirements or provide a justification for each cost item. Different organisation of costs made it hard for the Claimant to assess the specific need for each study and its cost and the relevance of the requested administrative costs for the Claimant's registration. The Claimant challenged the provided information and requested further details on the administrative costs[15].

29. The Other Party's answers[16] to the Claimant's questions were of a general nature (e.g. '*considering that there is a co-leader, an extra cost* [has] *been considered for this consortium management*') and did not indicate how the administrative cost items were linked to the

[10] The Claimant, 13 December 2017 & 16 January 2018.
[11] The Claimant, 8 March 2018.
[12] The Other Party, 16 January 2018.
[13] The Claimant, 17 January 2018.
[14] The Other Party, 19 February 2018.
[15] The Claimant, 19 February 2018.
[16] The Other Party, 5 March 2018.

[redacted]

Claimant's registration. The Claimant explicitly referenced Article 2 of the Implementing Regulation 2016/9 by stating that the provided cost-sharing information had not been transparent.[17]

30. Following the Claimant's request on 8 March 2018, the third cost-sharing table was soon provided to them[18]. The table indicated [redacted] study costs and [redacted] administrative cost items without explanations on their relation to the Claimant's tonnage band. Instead, the table indicated that all the co-registrants, regardless of tonnage band, shared the same study and administrative costs.

31. As the information provided to the Claimant was not answering the Claimant's questions but rather re-organising the cost differently in each table, the Other Party did not make every effort to provide information on the administrative costs. Consequently, The Other Party could have made more efforts by providing the most-detailed cost calculation table (from 14 March 2018) to the Claimant without undue delay following their initial request in December 2017[19], in view of the approaching REACH registration deadline of 31 May 2018. Without these efforts, the Claimant was not able to understand how the administrative costs had incurred and assess objectively the requested price. In this respect, the Other Party did not make every effort in the negotiations.

32. As a consequence, the Claimant was not able to assess whether the indicated administrative costs were required to be shared in their tonnage band. The Other Party did not provide information to the Claimant on the administrative costs they needed to satisfy their registration requirements set out in the Implementing Regulation 2016/9. Therefore, the Other Party failed to comply with their obligation to make every effort and the Claimant made more efforts to reach an agreement on the conditions to access the joint submission and the related costs in a transparent way as required by REACH and the Implementing Regulation 2016/9.

D. Conclusion

33. Neither party made every effort to reach an agreement on sharing the cost of [redacted] study.

34. Regarding the administrative costs, the Claimant made every effort to reach an agreement on access to the joint submission and the sharing of information. It provided timely comments and challenged the Other Party's itemisation of administrative costs repeatedly. The Other Party did not make every effort, because it provided inconsistent information on how the administrative costs had incurred and how they related to the Claimant's registration requirements. In light of the REACH registration deadline of 31 May 2018 and considering the dispute submission as the last resort for the Claimant to get access to the joint submission before the deadline, the Claimant made every effort in the negotiations overall.

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

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[17] The Claimant, 8 March 2018.
[18] The Other Party, 14 March 2018.
[19] The Claimant, 13 December 2018.