[redacted]

Helsinki, 28 November 2019

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

Acting on behalf of
The Lead Registrant,

[redacted]

Sent via REACH-IT

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 THE SHARING OF DATA

A. Decision

Based on Article 27(6) 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

[redacted]

ECHA grants the Claimant permission to refer to information requested from the Other Party for the purpose of a registration under the REACH Regulation.

The reasons for this decision are set out in Annex I. The list of studies that ECHA grants permission to refer to, along with copies of the (robust) study summaries, can be found in Annexes II and III, respectively.

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

B. Observations

The information requirements of REACH Annexes VI-X apply to registrations, depending on the volume. The present decision will not cover all the Claimant's information needs.

Despite the present decision, both parties are still free to reach a voluntary agreement. ECHA strongly encourages the parties to negotiate further in order to reach an agreement that will be satisfactory for both parties.

According to Article 27(6) of the REACH Regulation, the Other Party shall have a claim on the Claimant for an equal share of the cost, which shall be enforceable in the national courts, provided that the Other Party makes the full study report or reports available to the Claimant.

Instructions to the Claimant on how to submit the registration dossier making use of the permission to refer are provided in Annex IV.

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.

Authorised[4] by Minna Heikkilä, Head of Legal Affairs

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 communication has been approved according to 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 27(5) of the REACH Regulation, ECHA performs an assessment of the efforts of the parties to reach an agreement (Article 5 of Commission Implementing Regulation 2016/9). According to Article 27(6) of the REACH Regulation and Article 3(2) of the Implementing Regulation 2016/9, ECHA may grant permission to refer to the requested studies, if the claimant has made every effort to find an agreement on the sharing of the data and the access to the joint submission and the other party has failed to do so. The permission to refer is subject to the proof that the potential registrant has paid a share of the costs incurred by the previous registrant(s).

2. The obligation to make every effort to find an agreement that is fair, transparent and non-discriminatory is laid down in Articles 27(2) and 27(3) of the REACH Regulation. It is further defined in Articles 2 and 4 of the Commission Implementing Regulation 2016/9.

3. Making every effort means that the 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 position of the other side 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 a 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 justifying the costs presented, and providing the necessary evidence and information to substantiate such costs, in order to reach a fair, transparent and non-discriminatory agreement and fair and transparent costs.

B. Summary of facts

1. This summary of facts is based on the documentary evidence submitted by the Claimant on 26 June 2019 and by the Other Party on 9 July 2019.

2. On 3 December 2018, the Claimant contacted the Other Party, stating it wished to import the Substance and asking for the Letter of Access (LoA) costs for [redacted], and corresponding cost split, in line with Commission Implementing Regulation 2016/9.

3. After settling that the Claimant had an inquiry number for the Substance, the Other Party indicated the total LoA costs for the [redacted], adding that the costs were based on sharing between two companies, and that there was an '*annual interest fee*' since the Other Party registered.[5]

4. The Claimant clarified that it intended to register at [redacted], asking for the corresponding LoA and cost split per tonnage band.[6]

[5] E-mail from the Other Party; 14 December 2018.

[6] E-mail from the Claimant; 14 December 2018.

[redacted]

5. The Other Party provided '*cost composition details*';[7] the Claimant replied with a request '*for a transparent cost split*' and a complete list of studies, per endpoint and Annex, which would allow it to judge whether all data is relevant and the costs justified.[8]

6. The Claimant noted that, according to the dissemination portal and registration dossier, the Other Party had '*used a lot of handbook data, publications and QSAR for most of the endpoints*'. The Claimant thus presented a table of costs based on the Fleischer list, adding that it might favour an opt-out.[9]

7. The Other Party sent the Claimant a more detailed cost calculation in March 2019.[10] The Claimant replied that the costs were high, that some administrative costs seemed to be duplicated (e.g., some costs for data search and data gap analysis would be added to the costs for IUCLID work), that the SIEF management cost was not justified for a small SIEF and that the costs for CSA and CSR were not substantiated. It added that it disagreed with the 3% annual increase fee.[11]

8. The Other Party replied that the data search and data gap analysis costs and the IUCLID work are different, and thus the fees are listed separately. As for the SIEF management fee, the Other Party stated that it was meant to cover all the Lead Registrant work, from 2011 to 2013, and that the costs are calculated in efforts by hours, with an hourly rate of [redacted] Euro. With regard to the annual increase fee, the Other Party explained that it was meant to balance the interest invested by the Lead Registrant in the process, and that not charging it would put earlier registrants at disadvantage.[12]

9. The Claimant reacted by stating that the rationale for the cost sharing model was not transparent, and that it was not in line with Commission Implementing Regulation 2016/9 to '*share costs that are only relevant to the [Lead Registrant]*'. As for specific issues, the Claimant criticised the fact that the Other Party had added costs for read-across in the 'data list', and it asked the Other Party to provide '*a transparent overview of studies, study related (monitoring) costs, IUCLID work and other justified admin and SIEF communication costs*', so that it could '*assess the adequacy of the proposed costs and decide where to opt-out, if necessary*'. The Claimant agreed with the sum presented for the IUCLID dossier; however, it argued that other costs were not transparent, since the lump sums presented did not allow for calculation in case of opt-out from individual studies. With regard to the SIEF management costs, the Claimant asked the Other Party to provide '*time sheets or a similar justification*', since it was of the opinion that co-registrants must not pay '*for consultancy costs related to the [Lead Registrant] strategy and his internal discussions*'. Finally, the Claimant complained about the annual increase, stating it was not justified, as well as some of the administrative costs, which it believed were duplicated. The Claimant requested '*a transparent cost overview*', otherwise it '*would need to ask ECHA for assistance*'.[13]

10. The Other Party replied that the administrative costs were calculated '*by hours and efforts invested into the [Lead Registrant] project*', and that it had provided '*every item of admin cost's details work in [its] last email already*', adding that it would be impossible to separate

[7] E-mail from the Other Party; 17 December 2018.
[8] E-mail from the Claimant; 17 December 2018.
[9] E-mail from the Claimant; 14 February 2019.
[10] E-mail from the Other Party; 1 March 2019.
[11] E-mail from the Claimant; 23 April 2019.
[12] E-mail from the Other Party; 25 April 2019.
[13] E-mail from the Claimant; 26 April 2019.

[redacted]

the work per endpoint or study. In this regard, the Other Party suggested that the Claimant could do its own data gap analysis and indicate which data it wished to purchase. As for the administrative costs, the Other Party stated that it had already provided the details of the LoA cost calculation. With regard to the annual fee, the Other Party reiterated that this was a common practice, providing examples of consortia which use such fees.[14]

11. The Claimant came back to the Other Party at the end of May, stating that it understood that the Other Party '*did not see the necessity to adjust [its] LoA cost sharing model*', in particular by not assigning certain costs to the respective individual studies, and handling such costs and the SIEF management fee '*in a rather non-transparent way*'. The Claimant moreover expressed again its disagreement with the '*3% annual increase fee*', stating it was not justified, and that all of this did not allow it to judge '*whether or not [the Other Party's] calculation is fair and in the interest of [the Claimant's] client*'. However, the Claimant stated that it was '*interested to find a compromise*', and proposed to '*live with some smaller inconsistencies and duplicated costs*', provided the Other Party would offer evidence to justify the SIEF management costs. It furthermore suggested not paying the annual fee of 3%, which it believed amounted to a '*penalty for late-joiners*' contrary to Commission Implementing Regulation 2016/9. The Claimant thus made a counter-proposal with the sums to pay, subtracting the above mentioned elements, and stating that, if the Other Party could not accept it, it would introduce a data sharing dispute with ECHA.[15]

12. The Other Party replied by saying no costs were duplicated. It added that, as described before, the SIEF management fee was '*calculated based on* [redacted] *and amount of time engaged is* [redacted] *(result is* [redacted]*)*', which was, in its opinion, a small number of hours for a project '*to complete registration in almost two years*'. The Other Party added it did not know '*what else detailed information [the Lead registrant] could provide [the Claimant] for the LoA calculation*' and as such it had '*no choice but wait for the decision from ECHA to judge on this point*'.[16]

13. On 26 June 2019, the Claimant submitted a claim under Article 27 of the REACH Regulation concerning the failure to reach an agreement on the sharing of data with the Other Party.

14. On 2 August 2019, ECHA informed both parties of its assessment of their efforts. The Claimant did not inform ECHA of any agreement voluntarily reached by the parties. The Claimant provided a proof of payment of a share of the costs to ECHA on 17 November 2019.

C. Assessment

15. As stems from the last e-mails from both the Claimant and the Other Party, a disagreement on two specific issues persisted throughout the negotiations and ultimately blocked their progress, bringing them to a standstill. The two issues are the annual interest fee and the SIEF management costs.

a. The '3% annual increase'

16. The Other Party informed the Claimant, from the beginning of the negotiations, that an '*annual interest fee*' since the registration year would be added to the LoA cost.[17]

[14] E-mail from the Other Party; 30 April 2019.
[15] E-mail from the Claimant; 31 May 2019.
[16] E-mail from the Other Party; 4 June 2019.
[17] E-mail from the Other Party; 14 December 2018.

17. Data and cost sharing must be transparent, fair and non-discriminatory. These requirements also apply to an annual interest rate, as set up by the Other Party. This entails that any such rate must have a clear purpose and a reason for being set at a certain percentage, so as to be transparent. Moreover, the rate set must not discriminate between registrants and be objectively justified.

18. The justification offered by the Other Party was that '*[t]he annual increase is in order to balance the interest [the Lead Registrant] invested already and the work after the registration*', and that such annual increase was common in most consortia.[18] The Other Party, however, did not explain any further how this rate was set, never offering the reasoning for the specific percentage or demonstrating the costs quantified, or the relationship between such costs and the rate established. The Other Party thus failed to transparently describe the cost and how it is relevant to the Claimant, or how the Claimant would benefit from it.

19. While the Claimant challenged this cost element and its justification, mentioning the Commission Implementing Regulation 2016/9 in support of its argument,[19] the Other Party simply claimed that such a rate was usual, without justifying it, and did not make any effort to provide further clarifications.

b. The SIEF management costs

20. With regard to the administrative costs of [redacted] assigned to SIEF management, the Claimant suggested that the amount proposed was not justified for a SIEF that consists of only [redacted] registrants. It added that '*costs for the opt-out discussions*' should not be shared by all registrants, but rather charged to the opt-out registrant. As a result, the Claimant asked for a new breakdown and justification of the SIEF management costs in accordance with ECHA Guidance on Data Sharing.[20]

21. The Other Party reacted by noting that such costs were designed to '*cover the work to run the [Lead Registrant] project in the whole process*', and that it contained '*all the time and effort for SIEF management, meetings between the [Lead Registrant] and third technical support company, use survey, SIP survey and so on*'.[21] The amount would be the result of a [redacted] fee, multiplied by [redacted].

22. The Claimant challenged this justification, arguing that co-registrants should not be required to pay '*for the consultancy costs related to the [Lead Registrant] strategy and his internal discussions, if that is not related to the co-registration*'.[22] It stated it needed to '*understand if theses [sic] costs are justified and applicable to [its] client*', and '*not just duplicated costs or used to cover expenses that were only applicable to the [Lead Registrant]*'.[23] The Claimant suggested that the Other Party would provide '*time-sheets or a similar justification*' to explain the costs.[24]

23. In reply, the Other Party did not explain the costs to show that there was no duplication, nor how they related to the Claimant's data requirements or how the Claimant benefitted from the expenses. It merely made a claim that [redacted] *hours for SIEF management is really*

[18] E-mail from the Other Party; 25 April 2019.
[19] E-mail from the Claimant; 31 May 2019.
[20] E-mail from the Claimant; 23 April 2019.
[21] E-mail from the Other Party; 25 April 2019.
[22] E-mail from the Claimant; 26 April 2019.
[23] E-mail from the Claimant; 31 May 2019.
[24] E-mail from the Claimant; 26 April 2019.

[redacted]

low for a [Lead Registrant] project to complete registration in almost 2 years', and that in case the Claimant would want a detailed account of '*all the history activity including every mails [sic] [the Lead Registrant] sent to communicate with the SIEF members, meetings and documents made, it may lead to lots of time to collect thus work contents*'.[25] Effectively, this reply left it open how the Other Party could ever establish that the costs would be costs that should be shared by all registrants.

24. The Claimant questioned the costs and justified the need to understand them. Suggesting that time-sheets would be provided can be a sensible step for a cost which is presented as hourly. The Other Party, however, failed to provide detailed justifications of the work done. It never explained, for example, which technical support company it was referring to, or how that work was needed for the SIEF. Thereby, the Other Party did not show how the costs were justified and applicable to the Claimant. The generic justification offered thus failed to provide a transparent account of the costs covered by this entry.

c. Conclusion on the negotiations

25. The parties discussed the cost elements point by point. Both parties replied to one another consistently, without unjustified delays occurring. After receiving the details on the LoA costs, the Claimant posed detailed questions to understand the cost calculation and which costs were relevant for its own registration. It also made the effort to try to approach the Other Party's proposal. This is namely visible by the fact that the Claimant had doubts over some costs and their potential duplication, but ended up accepting certain sums as reasonable,[26] and stated it '*could live with some smaller inconsistencies and duplicated costs*' so as '*to find a compromise without the need to involve ECHA*'.[27]

26. This attests to the fact that the Claimant made every effort to negotiate further and reach an agreement. Ultimately, it presented a counter-proposal, explaining its opt-out intentions and the rationale for the cost calculation, and tried to bridge the gap between itself and the Other Party. By not replying to that proposal, maintaining the same arguments and not presenting transparent justifications for the annual increase and the SIEF management costs, the Other Party did not make every effort to find an agreement on a fair, transparent and non-discriminatory sharing of the LoA costs.

D. Conclusion

27. The Claimant made every effort to reach an agreement on the sharing of information, while the Other Party did not make every effort. The Claimant also provided a proof of payment of costs.

28. Therefore, ECHA grants the Claimant permission to refer to the studies specified in the Annex II.

[25] E-mail from the Other Party; 4 June 2019.
[26] E-mail from the Claimant; 26 April 2019, with regard to the lump sum for the IUCLID dossier.
[27] E-mail from the Claimant; 31 May 2019.