[redacted]

Helsinki, 25 May 2018

The Claimant

[redacted]

Sent via REACH-IT

Copy to:
The Other Party

[redacted]

Represented by

[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 ACCESS TO A JOINT SUBMISSION AND THE SHARING OF DATA

A. Decision

Based on Article 27(6) of Regulation (EC) No 1907/2006 ('REACH Regulation')[1],

ECHA grants you permission to refer to the information you requested from the

[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.

[redacted]

Existing Registrant of the Substance and access to the joint submission.

This decision is adopted under Articles 27(6) and 11 of Regulation (EC) No 1907/2006 ('REACH Regulation')[2] 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')[3].

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[4].

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 27(6) of 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.

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[5]

Director of Registration

[2] 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.

[3] 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.

[4] Available at https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach.

[5] 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 27(5) 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 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 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. 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. Under Article 11 of the REACH Regulation and Article 3 of the Commission Implementing Regulation, all registrants of the same substance must be part of the same registration ('joint submission obligation') and share the costs related to the joint submission.

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.

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 12 March 2018 and by the Other Party on 29 March 2018.

6. On 21 December 2017, the Claimant contacted the Other Party expressing their interest to join the registration for the substance in question for [redacted] tonnage band. The Claimant asked for *'cost and modality to purchase the Letter of Access'.*[6]

7. On the same day, the representative of the Other Party (referred to as the 'Other Party' from now on) responded that for the substance in question they are responsible to negotiate data-sharing. They also quoted a LoA cost of [redacted] euros, and stated that *'the* [redacted] *includes a template CSR, although no charge is made for the CSR because the substance is not classified for* [redacted] *endpoints'.*[7] In addition, the Other party provided cost details in a separate spreadsheet, and informed that in case the Claimant wants to purchase the LoA, they have to *'complete the attached purchase form, and complete and sign the attached SIEF agreement and return both by email'.*[8] They also stated that they will not issue Letters of

[6] Claimant, 21 December 2017
[7] Other Party, 21 December 2017
[8] Other Party, 21 December 2017

[redacted]

Access in 2017 anymore but they will *'respond to further requests or ongoing queries early in January 2018'.*[9]

8. On 26 January 2018 the Claimant asked whether there will be *'a recalculation of LoA cost'*[10] since REACH-IT indicates that [redacted] companies already registered the substance, but the spreadsheet the Other Party provided indicated only [redacted] They also asked for the LoA costs for the tonnage bands [redacted] tpa and [redacted] tpa.

9. The Other Party responded on the same day that the [redacted] company *'registered late December 2017* [and] *unfortunately it is not possible to recalculate LOA costs after every new member joins'* as it would increase administrative costs for everyone. They also state that *'a reconciliation is planned for after the May 2018 deadline to account for registrations made recently and in the coming months',* and thus the costs provided are valid for now. The Other Party informed the Claimant that the substance is *'subject to an evaluation process by ECHA'* and thus there will be *'new studies costs and dossier updates'*, which shall be distributed in the reconciliation *'once the total number of registrants is known'*.[11]

10. On 7 February 2018, the Claimant responded with a brief summary of the negotiations so far, and expressed their concerns *'with particular reference to the compliance of* [the Other Party's] *proposal with the provisions of the current European Directives'*. The Claimant stated they *'cannot understand most of data and information contained* in [the Other Party's] *file, the form in which they are presented, the costs structure and the logic adopted for spreading them out over the different tonnage categories'.*[12]

11. The Claimant raised four points specifically.

    - First, the file provided for them was locked.
    - Second, they commented that the prices are based on the Other Party's internal costs and thus not *'justified and/or proved by supporting documents (invoices)'*.
    - Third, the Claimant stated that annual interest rate of [redacted] % is not *'in line with the document ECHA-17-B-05 "Typical cost elements in data sharing"'*.
    - Finally, the Claimant commented that *'economic impact of LoA fees on the unit costs of the* [substance in question] *is completely out of proportion if the different annual tonnage categories are compared'*, and stated that the impact is much greater on the lower tonnage bands than on the higher categories.[13]

12. The Claimant had also calculated the *'weight of the LoA fees on different tonnage bands'* as follows: *'1-10 tons* […] *= up to EUR* [redacted] *per kg, 10-100 Tons* […] *= up to EUR* [redacted] *per kg, 100-1000 Tons* […] *= up to EUR* [redacted] *per kg, and Over 1000 Tons* […] *= up to EUR* [redacted] *per kg'.* The Claimant stated that registration costs quoted by the Other Party are not proportional and strongly penalise *'the smaller tonnages with which small companies like* [the Claimant's] *are operating'* and such *'un-proportional market distortion will exclude* [the Claimant's] *company from any possible business negotiations with negative occupational*

[9] Other Party, 21 December 2017
[10] Claimant, 26 January 2018
[11] Other Party, 26 January 2018
[12] Claimant, 7 February 2018
[13] Claimant, 7 February 2018

[redacted]

impacts for [the Claimant's] *workers'*.[14]

13. The Claimant also provided links to the ECHA webpage and the REACH Regulation, and asked to provide more information to the points they raised, and to *'review the distribution of registration costs on the different categories according to more equitable and shareable criteria, less penalizing for small Companies that would otherwise risk an unfair exclusion from the EU market'.*[15]

14. On 15 February 2018, the Other Party responded by providing an unlocked copy of their cost spreadsheet, which included costs for several different substances, detailed study costs and information about how the costs are calculated. They also explained that the spreadsheet is *'an extract from a much larger cost calculation and reconciliation workbook'*, but that the *'LOA cost sheet as it stands does provide breakdowns of study costs per endpoint'*.[16] The Other Party stated that individual study costs are based on actual study costs, except if they are not available, then *'standard laboratory or Fleischer costs are used'*. The Other Party explained that for the substance in question the costs may exceed Fleischer costs because *'adapted methods are needed'.* Finally they explained that *'studies are assigned by tonnage band, so only costs relevant for each testing band are applied, and then the costs for each tonnage band are equally split between the registrants that need that information'*. Concerning the dossier preparation costs the Other Party stated that Consortium Members agreed a fixed fee of [redacted] euros *'for all substances in the scope of the consortium based on actual experience preparing the dossiers'* and that *'each registrant only pays a share of the €[redacted] dossier cost, and registrants in the higher tonnage bands pay a substantially greater share than those in lower tonnage bands'*.[17]

15. Furthermore, the Other Party stated that the annual interest rate is *'to ensure early registrants are not disadvantaged'* and that *'REACH guidance clearly allows the consortium to charge an interest rate to compensate the study owners for the substantial investment they have made'.*[18] The Other Party stated further that the interest of [redacted] percent is '*reasonable and lower than commercial interest rates'.* Finally, the Other Party stated that the *'burden of cost under REACH* [is] *unfortunately not something that can be addressed within the scope of individual registrations'*, and that it is '*unavoidable that registrants at the upper and lower end of a tonnage band have the same data requirements and have to bear the same share of costs, while registrants at the top of one tonnage band and the bottom of the next tonnage band might have quite significantly different costs despite a very small tonnage difference'*.[19] The Other Party also pointed out that each registrant will only pay a proportional share of study costs which are required in their tonnage band, and *'for the general costs weighting factors are applied to account for the different tonnage bands'.* With the same email, the Other Party also informed the Claimant that the costs do not yet include *'further work and new costs* […] *incurred since 2013'* following new data requests from ECHA, and that also the evaluation process might bring additional study requests and thus costs to registrants.[20]

16. On 19 February 2018, the Claimant thanked for the information, which '*unfortunately did not match* [the Claimant's] *expectations*'. The Claimant asked for more information about the '*additional request coming from ECHA; list of the new request, date and reasons of the request, amount of the additional costs and reason why they are not yet published after*

[14] Claimant, 7 February 2018
[15] Claimant, 7 February 2018
[16] Other Party, 15 February 2018
[17] Other Party, 15 February 2018
[18] Other Party, 15 February 2018
[19] Other Party, 15 February 2018
[20] Other Party, 15 February 2018

[redacted]

5years'.[21]

17. On 20 February 2018, the Other Party responded with a link to the evaluation decision and stated that the process is still ongoing as the registrants try to justify to ECHA that further testing is not required and that they already have adequate data to meet the data requirements. As amending the cost sharing scheme would require a *'vote of the Steering Committee of* [the Consortium]*'*, the Other Party has tried to save administrative costs and refrained from calling such meeting. Finally the Other Party stated that possible new costs would *'predominantly concern tonnages above* [redacted] *and so would not be relevant for* [the Claimant's] *envisaged registration'.*[22]

18. The Claimant replied on 20 February 2018 that *'eventual additional costs are for the category* [redacted] *or above and not as reported by* [the Other Party] *for* [redacted]*'.*[23] The Claimant asked when and how the Other Party is going to handle reimbursement. Finally, the Claimant referred back to the Other Party's email of 15 February 2018, and stated that they still *'retain the applicate prices as distortion of market in advantage of* [big] *company against small companies'.* For reference the Claimant calculated that *'cost for the category* [redacted] *is* [redacted] *times high*[er] *than* [redacted] [redacted] […and] [redacted] *is* [redacted] *high*[er] *than* [redacted] *tons or above'*.[24]

19. On 26 February 2018, the Other Party replied that the additionally requested studies are listed in Annex [redacted] of REACH and thus not required for the Claimant's tonnage band. The Other Party explained that they expect to complete the reimbursement in 2018, including *'the post 2013 costs',* and the costs will be recalculated so that *'study costs are shared between the number of registrants who require that study for their respective tonnage band, and the general costs are weighted according to each registrant's tonnage band, with higher tonnage bands paying a greater share'.*[25] Concerning their method of calculating the LoA, the Other Party assured they have developed the method using available guidance, it conforms to the Guidance on data-sharing and *'considerations on the fairness of a model based on volume factors are presented in* […] *report by the European Commission 'Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs'*. Finally the Other Party stated that the *'ratio will shift even further in favour of the lower tonnage bands'* and that additional studies *'concern the highest two tonnage bands'*.[26]

20. On 5 March 2018 the Claimant responded that the LoA cost still does not match with their expectation, and that the required amount of [redacted] euros *'is bringing* [the Claimant's] [the substance in question] *price out of any possible negotiation with clients'*. The Claimant also repeated their calculations for the kilogram prices for each tonnage band.[27] Finally they stated their intention to file a dispute to ECHA.

21. On 12 March 2018, the Claimant submitted a claim under Article 27 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.

22. On 23 May 2018, the Claimant provided a proof of payment amounting to [redacted] EUR.

[21] Claimant, 19 February 2018
[22] Other Party, 20 February 2018
[23] Claimant, 20 February 2018
[24] Claimant, 20 February 2018
[25] Other Party, 26 February 2018
[26] Other Party, 26 February 2018
[27] Claimant, 5 March 2018. (See also references to emails on 7 and 20 February 2018)

[redacted]

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. Article 27(2) of REACH Regulation imposes an obligation to existing and potential registrants to make every effort to reach an agreement on sharing of information. Furthermore, Article 27(3) of REACH as further detailed by the Commission Implementing Regulation, obligates parties to determine costs related to data sharing in a fair, transparent and non-discriminatory manner, and clarifies that each party only needs to pay for the data they need to fulfil the information requirements applicable for their registration. Further, the Commission Implementing Regulation provides minimum requirements for the parties to discuss during their negotiations, such as the cost sharing principles, covering also potential additional future costs, and a reimbursement scheme when new registrants join the registration. It also requires the existing registrants to provide upon request an itemisation of data and administrative costs including justifications of all cost items.

25. In this context, making every effort means that parties have to actively seek a common understanding of the data and its costs and on the principles for sharing them. Therefore, in data-sharing negotiations, the existing registrant has the obligation to provide sufficient information so that the potential registrant has an objective basis to understand the actual costs and consider whether the requested costs correspond to items that are relevant for their registration. The existing registrant also needs to make every effort to present the costs in an understandable way.

26. In the present case, initially, both parties made efforts to reach an agreement: the Claimant requested the necessary information to understand the cost proposal, and in turn the Other Party provided a cost breakdown. When the Claimant had more detailed requests, the Other Party addressed these and gave additional explanations and information about their cost calculations. Thereby, both parties made efforts as required by REACH and the Commission Implementing Regulation.

27. However, despite these efforts, the parties were not able to reach an agreement on the following topics.

28. Firstly, the Claimant raised concerns with the Other Party's cost calculation which was based on the sharing of costs between [redacted] registrants. However, based on information that they retrieved from REACH-IT, the Claimant argued that they would be the [redacted] registrant in the joint submission. The Other Party responded that it is *'not possible to recalculate the LOA costs after every new member joins'* since that would make the administrative cost much higher and that *'reconciliation is planned'* after the May 2018 deadline only.[28]

29. After this, the Claimant challenged the Other Party's proposal concerning the reimbursement mechanism, which did not yet include concrete provisions whether and how e.g. the administrative costs will be compensated. According to Article 2 of the Commission Implementing Regulation, a data sharing agreement shall include a reimbursement mechanism. In spite of this, the Other Party did not explain the frequency of the future reimbursement, and the Other Party also did not indicate when the reimbursement will take place; they merely referred to a cost reconciliation after the 31 May 2018 registration deadline.

30. By rejecting the Claimant's request to adjust the price according to the current number of registrants, and by not providing all the information related to the reimbursement mechanism,

[28] Other Party, 26 January 2018

[redacted]

the Other Party showed a lack of effort to come to a fair and transparent agreement on this matter. Further to this, the lack of explanation related to the reimbursement mechanism prevented the Claimant from having accurate and complete information on which they could base their decision to register. Second, the Claimant raised concerns with the cost breakdown, and more specifically with the administrative costs listed therein. The cost breakdown was provided as an excel spreadsheet, which the Claimant struggled to understand, namely '*most of the data and information contained in* [the Other Party's] *file, the form they are presented, the costs structure and the logic adopted for spreading them out over the different tonnage categories'.*[29] The Claimant also stated the costs provided by the Other Party are difficult to analyse as they are based on the Other Party's internal costs and were not justified by supporting documents (e.g. invoices). The Other Party stated that a fixed fee of [redacted] euros for the preparation of the dossier was agreed by the Consortium members *'based on actual experience'*[30] rather than provable expenses, and the administrative costs distributed to the tonnage band based on weighting factors rather than objective actual expenses for tonnage band-related tasks.

31. The Claimant asked questions, commented on the lack of invoices and consistently raised concerns about a cost-sharing model that in their perception put an unjustified burden on the [redacted] tonnage band[31]. Thus, the Claimant made efforts to understand what they were asked to pay for.

32. The Other Party made efforts by explaining to the Claimant in more detail how the administrative costs are distributed across tonnage bands. They also referred to the fact that REACH uses tonnage bands to divide the obligations between the registrants, so they use the tonnage bands as bases to calculate the administrative costs.

33. However, the Other Party could have made more efforts by providing substance specific cost tables and administrative costs instead of excel tables reflecting the registration costs for several unrelated substances based on the 'experience' of the Consortium. Further to this, they did not respond to the Claimant or address all their concerns. They could have done that, e.g. by explaining why they were not calculating the costs based on invoices or how they estimated costs. This would have helped the Claimant understand whether they were going to pay only for costs related their information requirements. The failure of the Other Party to address the Claimant's questions and concerns shows a lack of effort from the Other Party's side to come to a fair and transparent agreement.

34. Lastly, the parties negotiated about the annual increase of the LoA price. The Claimant questioned the use of an annual interest rate and referred to publicly available guidance '*ECHA-17-B-05 "Typical Cost elements in data sharing"* in their reasoning. In the referred Guidance at the Annual price increases section it is stated: '*Make sure that you are not requested to pay for an increase of the price just because you register later than your co-registrants. Such increases - sometimes called 'latecomer's penalties' or 'early bird incentives' - are not allowed.'*[32] The Other Party tried to justify this annual [redacted]% increase with two different arguments: (i) they answered that such interest is allowed by referring to *'ECHA guidance';* and (ii) they stated that the purpose is to avoid disadvantaging the previous registrants.

35. With this answer, the Other Party however did not respond to the Claimant's concern. The first argument does not reply to the Claimant's challenge, but merely claims the opposite.

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[29] Claimant, 7 February 2018

[30] Other Party, 15 February 2018

[31] Claimant, 7 February 2018, 20 February 2018 & 5 March 2018

[32] In A-017-2013, the Board of Appeal decided '[…]In this respect, the Board of Appeal considers that an additional charge which is to be paid only by registrants who purchase the letter of access after 2010 is de facto discriminatory unless there are legitimate and justifiable reasons for charging additional amounts to later registrants.'

[redacted]

The second argument is a variation of the justification for an increase that the document dismisses.

36. It follows that the Other Party did not make every effort to provide a substantial reply to the Claimant's concern that would objectively justify and explain to the Claimant the purpose and necessity of their interest rate that makes the price every year higher for the new registrants. Thus the Other Party failed to make every effort to come to a fair and non-discriminatory agreement.

D. Conclusion

37. By the time the dispute was filed, the Claimant had not received satisfactory answers and justifications to their concerns about the costs and were thus unable to assess their fairness objectively.

38. Based on the above, ECHA concludes that the Other Party breached their obligations under the Commission Implementing Regulation and did not make every effort to reach an agreement on data sharing and access to the joint submission in a fair and transparent way.

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