[redacted]

Helsinki, 28 November 2018

The Claimant

[redacted]

Represented by

[redacted]

Copy to:
The Other Party

[redacted]

Represented by

[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 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

[redacted]

('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.

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

B. Recommendation

Under Articles 30 and 11 of the REACH Regulation and the Implementing Regulation (EU) 2016/9, the parties must still make every effort to reach an agreement on the sharing of the information and costs related to 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 (i.e., the date of submission of the dispute claim).

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-Musset[4]

Director of Registration

[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.

[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.

B. Summary of facts

4. This summary of facts is based on the documentary evidence submitted by the Claimant on 3 May 2018 and by the Other Party on 19 May 2018.

5. On 10 April 2017, the Claimant contacted the Other Party, asking for the Letter of Access (LoA) costs, including the cost breakdowns, for the Substance for the tonnage bands [redacted], '*along with the scope of joint submission and SIEF agreement*', in order for their client to decide on registration. The Claimant then sent three reminders to the Other Party.[5]

6. The Other Party responded on 8 June 2017, and stated that the colleague responsible for the substance would respond once they were back in the office on 14 June. On 14 June 2017, the Other Party asked the Claimant, before providing the LoA costs, to '*kindly indicate which non-EU company [the Claimant is] on behalf for [the Other Party] to make a simple record?*'. The Claimant responded the same day with the non-EU company's details, and again requested the LoA.

7. After a reminder from the Claimant on 19 June 2017, on 20 June 2017 the Other Party provided the LoA costs '*in 2017*' for non-[redacted] members for [redacted] tpa. The Claimant replied the same day,

[5] Claimant; 20 April 2017, 24 April 2017, and 7 June 2017.

[redacted]

and asked for the cost breakdowns of the LoAs to '*enable [the Claimant's] client to decide upon the registration*' of the Substance.[6]

8. The Claimant sent two reminders to the Other Party.[7] On 19 July 2017, the Claimant informed the Other Party that their client was to become an [redacted] member, and asked for the applicable LoA costs for [redacted] members for [redacted] tpa and the cost breakdowns so that their client could decide upon registration.

9. The Claimant sent a reminder on 24 July 2017. The Other Party replied on 25 July 2017 that '[redacted] *[…] [the Other Party] will try [to collate] the fee […] and provide [the Claimant with] the details as soon as possible*.' The Claimant then sent an identical email to the Other Party on 25 July 2017 that it had sent on 19 July 2017, informing that their client was to become an [redacted] member and asking for the LoA costs mentioned in paragraph No. 9.

10. On 26 July 2017, the Other Party provided the LoA costs for [redacted] tpa, and stated that they would '*provide [the Claimant with] the LOA calculation details later*' for [redacted] members. The Claimant responded the same day, and asked for the '*tentative date*' as to when the cost breakdowns would be available so that their client could decide on registration.[8]

11. On 8 August 2017, the Claimant requested justifications from the Other Party for the LoA costs, stating that their '*client feel[s] that a lot of [the Substance] data is already available with* [redacted] *or [in the] public domain.*', and asked why the LoA costs were so '*high for the chemical which is used in day to day life.*' They also stated that '*The LOA cost for* [redacted] *and non-*[redacted] *members does not have much difference? But usually a* [redacted] *member has much less LOA cost compare[d] to Non* [redacted] *member*', and requested a '*clear justification*'. The Claimant sent two reminders to the Other Party for a response.[9]

12. On 12 October 2017, the Other Party responded, apologising for the delay and stating that the LoA calculation details would be available '*in the coming days*', as at that point their technical expert was '*busy dealing with the* [redacted].' On 16 October 2017, the Claimant said that as they had sent several reminders with no reply, they would file a dispute with ECHA if there was no '*response or explanation from your side […] [regarding] the cost break up*' by 18 October 2017.

13. The Other Party responded on 16 October 2017, stating that they had '*received the confirmation from the LR [of] the LOA cost for Non* [redacted] *member[s] adding the new testing studies […] which is valid before 30th December, 2017*'. They provided some cost breakdowns (for '*Administration items*' split to six activities; '*CSR preparation*'; '*LR studies*' and '*Third party studies*' per REACH annexes [redacted]; and '*Preparing the registration dossier*' per tonnage band) and the cost of studies for an [redacted] member, and said that the LoA costs would be recalculated after the 2018 deadline. The Claimant responded the same day, thanking the Other Party for the information and asking whether it was '*possible to send more details on what the specific studies conducted by the LR & third parties were?*' They said that they were '*hoping for a more detailed split since the above cost appears unreasonably high*'.[10]

14. On 17 October 2017 the Other Party replied, stating that they '*only have the information that*

[6] Claimant; 20 June 2017.
[7] Claimant; 27 June 2017 and 12 July 2017.
[8] Claimant; 26 July 2017.
[9] Claimant; 1 and 19 September 2017.
[10] Claimant; 16 October 2017.

[redacted]

the cost of studies related to [redacted] *member in total is €* [redacted]*. For the details of studies list, [the Other Party*] *will turn to LR to approach the information […] required'*, and that they would provide the Claimant with that information as soon as they received it. The Claimant replied the same day, stating they were '*Waiting for [the Other Party's] response.*'[11]

15. On 28 November 2017, the Claimant again informed the Other Party that their client was interested in registering for [redacted] *tpa'*, and asked the Other Party to '*kindly share [the] SIP and the letter of access cost details (which includes the cost breakup of the chemical) along with the scope of joint submission and SIEF agreement for the same. This will enable [the Claimant's] client to decide upon the registration of the above mentioned substance*.'

16. On 29 November 2017, the Other Party again provided the Claimant with the LoA costs for non-[redacted] members for [redacted] tpa. They noted that '*There will be an annual interest fee to be added at the beginning of 2018. [The Other Party] will recalculate the LOA cost after 2018 deadline*.'

17. On 6 December 2017, the Claimant requested the LoA cost breakdown for [redacted] tpa to enable their client to decide whether to register. The Claimant sent a reminder on 15 December 2017.

18. On 18 December 2017, the Other Party said that they had '*requested the information [the Claimant] need[s] again*' from the Lead Registrant, and that the '*responsible person promise[d] to provide […] the LOA details after the Christmas holidays.'*

19. On 3 January 2018, the Other Party sent the LoA cost breakdown.

20. On 22 January 2018, the Claimant said that '*as per the opinion of [the Claimant's] client the LOA cost for* [redacted] *tonnage band is too high'*, their client would like an opt-out token. They requested the '*administrative fee*' to receive a token.

21. The Other Party responded on 23 January 2018, and said that they had '*provided [the Claimant with] the LOA calculation details already. The cost of data sharing is fair and transparent.'* They asked which endpoints the Claimant wanted to opt-out of, as the Other Party would '*calculate the LOA cost on [the Claimant's] details of request.'* They also asked whether the Claimant had '*the existing data of the endpoints [the Claimant] would like to opt-out? In case [the Claimant] does not have the set of data, how [would the Claimant] opt-out these data and submit [the Claimant's] own? It is not complian[t] with REACH Regulation to submit a dossier without any data.'*

22. On 5 March 2018, the Claimant stated that their '*client is in possession of some data'* and that they were generating the required dataset regardless, for reasons other than registration. They said that their client '*would not require the data access from [the Other Party's] dossier*', and requested the cost for a token. The Claimant said that they looked forward to the Other Party's positive response and stated that *'If [the Claimant] do[es] not receive the desired details from [the Other Party's] end for opt-out, [the Claimant would] file the dispute at ECHA*.'

23. On 6 March 2018, the Other Party said that '*Of course, [the Claimant] could choose to opt out the data […] and submit the personal dossier. However, why [the Claimant] did not come back to [the Other Party when they] did the survey for the [existing] data of this substance [if the Claimant had] the data …?'*. They asked for a list of the data the Claimant's client '*really own[s] for this substance*', so that the Other Party could then '*calculate the LOA cost based*

[11] Claimant; 17 October 2017.

[redacted]

on [the Claimant's] special [situation].' The Other Party reminded the Claimant that they '*could not submit a[n] empty dossier with Placeholder Text instead of related data since it does not accords with REACH Regulation.*'

24. On 23 March 2018, the Claimant filed a dispute to ECHA, requesting a token for access to the joint submission while opting out for all the information requirements.[12] According to the Board of Appeal decision in case A-011-2017, *'the Agency must, when requested, give the 'token' to any registrant who informs it of its decision to rely on a complete opt-out in accordance with Article 11(3)*'[13]. On 22 May 2018, based on this decision of the Board of Appeal, ECHA gave the Claimant an opt-out token. ECHA also informed the Other Party of this.[14]

25. However, during this period before the token was granted, on 25 April 2018 the Claimant's representative, engaged due to '*the consistent [failures] to respond through the course*' of negotiations, contacted the Other Party and stated that the Claimant's email of 17 October 2017 (detailed above in paragraph No. 15) remained unanswered. They requested the '*Cost breakdown per study and proof of costs*', an '*Explanation of inconsistencies in costs provided to date*', and '*A draft SIEF agreement*' by 2 May 2018, otherwise they would file a dispute with ECHA. They pointed out the urgency of the issue due to the approaching REACH deadline of 31 May 2018, and noted also that the Claimant '*reserve[d] the right to bring these matters to the attention [of] the European Commission's DG Competition, given its legitimate concern that the repeated failure to respond to its request for mandatory information are driven by a desire to exclude it from the EU market for the Substance.'*

26. On 3 May 2018, the Claimant's representative contacted the Other Party again, noting their failure to respond and stating that they were '*therefore forced to initiate the data sharing dispute*' with ECHA. The same day, the Claimant's representative 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

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

28. Making every effort means to negotiate in a clear and constructive manner to enable parties to find a mutual understanding. This means asking questions about any concerns and replying constructively to each other's questions and concerns, and using the exchange of information effectively in order to find a common understanding on which an agreement can ultimately be based.

29. The negotiations between the parties had two phases. During the first phase the Claimant asked for full opt-out and during the second phase they seemingly had a registration strategy for sharing data.

<u>Phase 1: Registration strategy for full opt-out</u>

30. The first phase started when the Claimant contacted the Other Party and requested the LoA and cost breakdown. Pursuant to Article 2(2) of the Implementing Regulation (EU) 2016/9, the Other Party has to provide a breakdown of costs without undue delay. ECHA notes that it

[12] Based on [redacted], lodged with ECHA on [redacted]. The entirety of paragraph No. 24 is based on ECHA's own internal documentation, not on evidence provided by either party.

[13] Paragraph 44 of the Board of Appeal decision in case A-011-2017.

[14] ECHA communicated with both parties regarding the token on 22 May 2018.

[redacted]

took 10 months for the Other Party to provide the cost breakdown and the Other Party sent delayed responses in several instances, requiring the Claimant to send frequent reminders, especially at the beginning of negotiations in 2017. However, this needs to be put in perspective with the facts that this circumstance did not bring the negotiations to a standstill. The parties continued with negotiations and they still had time to discuss the cost breakdown before the registration deadline.

31. Once the Other Party provided the LoA costs and cost breakdown, the Claimant indicated that the requested price was too high and that they wanted to opt-out from the dossier. The Other Party asked the Claimant to explain which endpoints they wanted to opt-out from so that they could re-calculate the price. However, in their reply, the Claimant indicated only that their '*Client is in possession of some data*' and that they wanted to opt-out.

32. Even though the Claimant declined any further negotiation, the Other Party continued asking further details about the data the Claimant owned. The Claimant never provided a reply to these requests.

33. Based on the Claimant's statement that they would submit only their own information, the Other Party could legitimately expect that the negotiations with the Claimant on this substance were on a full opt-out strategy—i.e., the Claimant did not want to share data. This was confirmed when the Claimant filed a dispute requesting a token for access to the joint submission while opting out for all the information requirements. This statement of the Claimant and the lodging of the dispute closed the first phase of the negotiation between the parties.

Phase 2: Registration strategy for sharing data

34. The negotiations started anew on 25 April 2018, when the Claimant's representative contacted the Other Party. They stated that the Claimant had not received a reply to their email dated 17 October 2017 (sent during the first phase) and asked for the cost '*breakdown per study and proof of costs*' and an explanation of inconsistencies in the costs provided in October and a draft SIEF agreement. With this request, the Claimant's representative re-started the negotiations from an earlier point and requested information (except for the SIEF agreement) that was already provided by the Other Party.

35. During this second phase, ECHA found that the efforts regarding the following issues need to be assessed.

36. Firstly, ECHA notes that the Claimant submitted two dispute claims for the substance at hand, the first of which is detailed above in paragraph No. 24. However, the fact that the Claimant would need access to the joint submission for two different legal entities as Only Representative for different non-EU manufacturers was never explained to the Other Party. Based on the negotiations, the Other Party had the legitimate expectation that the Claimant was representing only one company. In order to avoid any confusion, the Claimant should have made the effort to inform the Other Party of the fact that they were representing two companies and restart the negotiations on this basis.

37. Secondly, when the Claimant's representative re-started the negotiations, the requested information contradicted the initial request made during the first phase. During the first phase, the Claimant informed the Other Party that they want to submit a full opt-out registration. During the second phase, the Claimant's representative asked for something different; however, they failed to explain to the Other Party that they had changed their view and why they wanted to re-start the negotiations with a different scope.

[redacted]

38. Thirdly, some of the information requested (i.e., a cost breakdown) had already been provided by the Other Party to the Claimant during the first phase of the negotiations.

39. Fourthly, the Claimant's representative gave only 8 days for the Other Party to reply to their request.

40. Fifthly, the Claimant's representative also failed to address the Other Party's concerns regarding what data the Claimant held. The Claimant did not mention that they held their own data until late in the negotiations during the first phase and did not specify what data that was, even after the Other Party specifically challenged the Claimant on it. ECHA notes that data sharing and submitting information jointly are core principles of REACH. By not answering the Other Party's questions, or, indeed, indicating in the first instance that they had their own data, the Claimant failed in their data-sharing obligation according to Article 29(3) of the REACH Regulation.

41. Sixthly, during the first phase the Claimant declined any subsequent discussion regarding the cost breakdown after they received the offer from the Other Party. Instead of pursuing a constructive approach to make sure that the negotiations moved forward swiftly, the Claimant indicated they had data and showed only intention to receive an 'opt-out token'. During the second phase, the Claimant's representative never requested further detailed information on how the cost of the LoA was calculated or challenged the Other Party's calculation. By not justifying any concern about the costs to the Other Party, the Claimant's representative did not make efforts to reach an agreement.

D. Conclusion

42. In light of the above, ECHA finds that the Claimant's representative did not submit this dispute as a measure of last resort. The Claimant's representative changed the scope of the negotiations without providing further explanation for the Other Party and asked for information that was partially already provided to the Claimant, while giving only 8 days to the Other Party to reply to the new request. The absence of any explanation created confusion; thus, they did not behave in a consistent, predictable and constructive manner.

43. Therefore, ECHA concludes that the Claimant did not make every effort to engage in meaningful discussions and advance the negotiations; hence, the Claimant failed to act in accordance with their obligation to make every effort to find an agreement with the Other Party. Consequently, ECHA does not grant the Claimant access to the joint submission or permission to refer to the studies.

[redacted]

Annex II: ADVICE AND FURTHER OBSERVATIONS[15]

If the Claimant requires access to the Other Party's information, the parties should continue the negotiations and aim to reach an agreement on the sharing of information.

[15] 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.