[redacted]

14 February 2019

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

Sent via REACH-IT

Reference number: [redacted]

DECISION ON A DISPUTE RELATED TO THE SHARING OF DATA

The European Chemicals Agency (ECHA) has examined the dispute claim and the information you submitted on 18 December 2018 with reference number [redacted], regarding the failure to reach an agreement with [redacted] ('the Other Party') on sharing of data pursuant to Article 27(5) of Regulation (EC) No 1907/2006 ('REACH Regulation')[1], for the substance [redacted] (the 'Substance') with EC number [redacted].

ECHA has examined the efforts of the parties to reach an agreement on the sharing of data and its costs in a fair, transparent and non-discriminatory way in accordance with their obligation under Article 27 of the REACH Regulation, as reinforced by Articles 2 to 4 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]. For this purpose, ECHA has assessed whether you have made every effort to find an agreement with the existing registrant.

A. Decision

[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]

On the basis of the documentation supplied, and pursuant to Article 5 of the Commission Implementing Regulation,

ECHA does not grant you the permission to refer to the information you requested from the Other Party.

This decision is adopted under Article 27(6) of the REACH Regulation and Article 5 of the Implementing Regulation 2016/9.

The reasons for this decision are set out in Annex I. Further advice and observations are given in Annex II.

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

B. 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: ASSESSMENT

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 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, 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 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 other party's position and consider it in the negotiations.

4. 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.

[redacted]

B. Summary of facts

1. This summary of facts is based on the documentary evidence submitted by the Claimant on 18 December 2018 and by the Other Party on 11 January 2019.

2. In May 2017, the Claimant asked the Other Party for the Letter of Access ('LoA') to the Substance, stating they wanted to register at [redacted].[5] The Other Party replied on 6 September 2017 that it intended to answer that message 'shortly'.[6] A month later, the Other Party wrote to the Claimant stating that, since records were not readily available, it would be difficult to estimate the exact costs. The Other Party suggested that the Claimant would opt-out due to the high costs and the fact that no one else had requested the LoA. It further suggested it could provide the services of an Only Representative for the Claimant.[7]

3. On 6 October 2017, the Claimant requested a detailed breakdown of the LoA costs, stating that it cannot opt-out due to the principle of 'One substance, one registration' ('OSOR'). It further requested the Substance Identity Profile ('SIP') covering the registration.[8] The Claimant then sent reminders of this request, finally suggesting to hold a teleconference.[9]

4. On 22 January 2018, B[redacted] sent an email to the Other Party. According to its letterheard, B[redacted] is an Amercian lawfirm. Its office in Washington DC has the [redacted] of the Claimant. The e-mail referred to a teleconference held between the Claimant and the Other Party on 7 December 2017. B[redacted] described its intention to facilitate discussions between the Claimant and the Other Party to ascertain substance sameness and proposed a non-disclosure agreement between itself and the Other Party. It annexed the non-disclosure agreement on the determination of the substance identity and sameness 'in a manner that protects [the Other Party]'s proprietary process and substance information'. It asked that the Other Party would sign it, further stating that if a chemist from the B[redacted] would find that the substances are not the same, the Claimant would proceed with registering the Substance separately. Otherwise, it would expect the Other Party to provide a 'reasonable Letter of Access cost for the Annex [redacted], no later than 16 February 2018'. They required the Other Party to reply by 25 January 2018.[10]

5. On that date, the Other Party replied that it had a LoA cost breakdown which it would be 'happy to share' with the Claimant. However, it had 'a problem with the information [that the Claimant was] requesting to check the sameness of [the] registered material to that' of the Claimant, since such information was 'highly proprietary and key to the competitive advantage of [its] technology'. The Other Party hence suggested that the Claimant would 'submit an inquiry dossier to ECHA and let the agency decide on the sameness'.[11]

6. The Claimant requested the costs of the LoA for Annex [redacted] and a detailed breakdown by 31 January 2018.[12] The Other Party sent the total costs for [redacted] on 30 January 2018.[13] The Claimant reacted by asking for the cost breakdown for

[5] E-mail of the Claimant, 10 May 2017.
[6] E-mail of the Other Party, 6 September 2017.
[7] E-mail of the Other Party, 4 October 2017.
[8] E-mail of the Claimant, 6 October 2017.
[9] E-mails of the Claimant, 2 November 2017 (asking for a reply by 13 November), 16 November 2017 and 1 December 2017.
[10] E-mail of B[redacted], on behalf of the Claimant, 22 January 2018.
[11] E-mail of the Other Party, 25 January 2018.
[12] E-mail of the Claimant, 26 January 2018.
[13] E-mail of the Other Party, 30 January 2018.

[redacted]

these values by 5 February 2018.[14]

7. On 6 April 2018, the Claimant sent an email to the Other Party complaining that the latter has 'repeatedly refused to provide details regarding the substance information profile, or even broad boundary composition of this substance, and has also failed to provide a transparent cost analysis for the letter of access costs'. It thus asked the Other Party for 'percentage ranges for each of the constituents listed by [the Other Party] in the public legal entity composition of the substance in its joint registration dossier' and the LoA cost details by 11 April 2018, adding that it did 'not find credible [the Other Party]'s claim that it cannot provide composition ranges for the constituents of this UVCB substance without compromising proprietary business information'.[15]

8. In response, the Other Party presented 'a summary of the issues' discussed with the Claimant's team. It stated that the Substance is manufactured by them 'utilizing a highly complex and proprietary process', and that 'the detailed composition' thereof is 'valuable confidential information and intellectual property of [the Other Party]'. They moreover pointed out that the Claimant's client is a direct competitor to the Other Party [redacted], and that 'so far, [the Claimant was] the only entity to have shown an interest to purchase a letter of access for [the Substance], and [it was] asking for compositional details to evaluate substance sameness'. This was cause for concern to the Other Party. It noted that it had indicated, 'on December 7, 2017', that a 'neutral third party' should be appointed to 'independently evaluate the analytical data from the two companies to assess substance sameness'. However, the non-disclosure agreement proposed by the Claimant 'created a conflict of interest and did not meet the neutral third party standard needed' since it was done with the Claimant's 'parent organization'. The Other Party stated that it was unsure whether the Claimant had submitted an inquiry to ECHA, as suggested, but added that 'once ECHA confirms the substance sameness, [it] would set up an LOA agreement with [the Claimant] and provide [the Claimant] with the detailed cost breakdown'.[16]

9. The Claimant replied on 2 May 2018, noting that it had filed a dispute claim with ECHA on 13 April 2018, but had been advised by the Agency that, in the aftermath of the decision of the Board of Appeal in Case A-011-2017, 'ECHA will not be in a position to process [redacted] dispute claim according to established procedures'.[17] The Claimant would hence wish, in light of the OSOR principle, to continue the negotiations with the Other Party so as to reach an agreement on the substance sameness and costs which would enable it to join the SIEF for the Substance. To that end, the Claimant suggested that the Other Party should 'appoint an independent trustee at its own expense (…) subject to [the Claimant]'s approval'. In addition, the Claimant stated that submitting an inquiry dossier to ECHA would be 'inappropriate as the substance has been pre-registered by' the Claimant. With regard to their own client, the Claimant stated that sharing information amongst competitors was 'an essential part of REACH', and that the behaviour of the Other Party constituted 'abuse of a dominant position'. Finally, the Claimant reiterated its previous request of 'an "itemization" or breakdown of costs per tonnage band', 'in accordance with REACH and Implementing Regulation (EU) 2016/9', as well as the

[14] E-mail of the Claimant, 2 February 2018.

[15] E-mail of the Claimant, 6 April 2018.

[16] E-mail of the Other Party, 10 April 2018.

[17] ECHA's notification to the parties of 25 May 2018 stated that 'Following the Board of Appeal decision [case A-011-2017], ECHA will not perform an assessment of the efforts of the parties in finding an agreement on the access to the joint submission in case of a full opt-out. (…) ECHA will issue a token to the full opt-out registrant so they can become a member of the joint submission.' Later, ECHA issued a token that allows the Claimant to join the joint submission, but not to share data.

[redacted]

Guidance on Data-sharing, since 'the costs provided appear high'.[18]

10. On 15 May 2018, the Other Party noted that its concerns with regard to sensitive information had been discussed already 'during a teleconference in December 2017', where the Other Party had recommended appointing an 'independent third party with the necessary technical expertise to assess substance sameness'. However, the Claimant had insisted on appointing its own parent company which was unacceptable. In addition, the Other Party stated that it had suggested that the Claimant would submit an inquiry dossier to ECHA. With regard to finding an independent third party, the Other Party told the Claimant that it had 'begun to reach out to a few consultants'. It finished by restating that 'once the sameness is established, [it] will provide [the Claimant] the LOA cost breakdown as part of the LOA agreement.'[19]

11. On 4 June 2018, the Other Party wrote to the Claimant with a proposal for a consultant as independent third party to conduct the substance sameness assessment, asking for the Claimant's agreement and stating that the Other Party would cover the expenses.[20] The Claimant replied that it was 'considering [the Other Party's] proposal and will circle back'.[21]

12. In the beginning of October, the Claimant sent a new email stating that it had 'submitted an inquiry dossier to ECHA for [their] client's substance and ECHA has determined that [their] client's substance is the same as the one registered by [the Other Party]'. It thus requested the Other Party to send the LoA costs for the Substance 'at the Annex [redacted] with a detailed breakdown of how these costs have been calculated by Friday, October 5, 2018.'[22]

13. The Other Party replied on 22 October 2018, stating that it had requested ECHA to confirm the substance sameness but ECHA had 'implied in its response that the Agency has not made any substance sameness determination'. The Other Party thus asked the Claimant to respond to the e-mail of 4 June 2018 regarding the proposal of third party involvement for the determination of substance sameness.[23]

14. On 18 December 2018, the Claimant submitted a claim under Article 27 of the REACH Regulation concerning the failure to reach an agreement on the sharing of information with the Other Party.

C. Assessment

15. As explained in section A, ECHA assesses the efforts made by the parties in the negotiations that have been outlined in section B.

16. The determination of substance sameness remained the contentious point in the negotiations since the beginning and was never resolved between the parties. This was an important preliminary step that would precede the discussions on sharing the studies themselves, because the Claimant needed to know whether the data would be useful for its registration, and the Other Party was only bound by data sharing obligations if the Claimant intended to register the same substance. The Substance is a UVCB which potentially made the substance sameness more complex. Moreover, the Other Party explained that it had a concern with disclosing the composition of its substance, because it would thus disclose confidential

[18] E-mail of the Claimant, 2 May 2018.
[19] E-mail of the Other Party, 15 May 2018.
[20] E-mail of the Other Party, 4 June 2018.
[21] E-mail of the Claimant, 6 June 2018.
[22] E-mail of the Claimant, 3 October 2018.
[23] E-mail of the Other Party, 22 October 2018.

[redacted]

business information.

17. In order to obtain clarity on the substance sameness without disclosing business secrets, the Other Party suggested an inquiry with ECHA. The Claimant suggested 'to set up an independent third party with the necessary technical expertise to assess substance sameness.'[24] Consequently, B[redacted] contacted the Other Party with a draft non-disclosure agreement. The Other Party, however, refused to sign it. It stated: 'As you must know, B[redacted] is the parent company of A[redacted]; thus it cannot be considered as an independent third party.'[25]

18. The Claimant reacted by asking that the Other Party would suggest and pay for a neutral third party, subject to the approval of the Claimant. In response, the Other Party proposed a third party consultant that it would pay for. In order to make every effort, the Claimant could have replied to this proposal, accepting it, outlining its concerns, if it had any, or to make another proposal. The Claimant, however, never replied to this proposal, nor did it present any counterproposal. Four months later, the Claimant responded that it had sent an inquiry to ECHA. ECHA confirmed that the substances appeared to be the same, but could not make a definitive assessment of the substance sameness in the inquiry process. When the parties realised that, the Other Party repeated its proposal to appoint and pay for a third party that the Claimant would agree with, to determine substance sameness.

19. Under these circumstances, it cannot be concluded that the Claimant made every effort to find an agreement or exhausted all the negotiation possibilities before submitting a data sharing dispute.

20. Conversely, while the Other Party was less responsive in the first part of the negotiations, it was engaged in the negotiations, as stems from paragraphs 10 and 11 above, by accepting the Claimant's proposal that it would appoint and pay for an independent third party to assess substance sameness. It moreover proposed a consultant, asking for the Claimant to agree. This is a clear effort from the Other Party, who was constructive in trying to find a solution which could be agreeable to both parties to clarify the substance identity.

21. By not responding to the Other Party's suggestion of contracting and paying for a neutral third party consultant to clarify the substance identity, the Claimant hindered the progress of the negotiations, and hence failed to make every effort to find an agreement that is fair, transparent and non-discriminatory in accordance with the REACH Regulation and the Implementing Regulation 2016/9.

D. Conclusion

22. The Claimant did not make every effort in the negotiations to reach an agreement with the Other Party. Therefore, ECHA does not grant the Claimant permission to refer to the data requested.

[24] E-Mail of the Other Party, 15 May 2018.

[25] *Ibidem*

[redacted]

Annex II: ADVICE AND FURTHER OBSERVATIONS[26]

- The Parties should continue the negotiations aiming to reach an agreement on the sharing of information. Both parties should make every effort to this end.

- As a first step to determine the usefulness of the data and whether the data sharing obligation under REACH applies, the parties have agreed to clarify whether they register the same substance. While details of the substance identity may be confidential in nature, a full disclosure of the substance identity is not always necessary in order to determine whether data can be used and whether substances are the 'same' in the context of the REACH Regulation.

- This decision does not prevent the Claimant from submitting a new dispute under Article 27(5) of the REACH Regulation in case further negotiations do not lead to an agreement on the sharing of data. It would need to demonstrate that it made every effort in contacting the Other Party, and that all the possible efforts and arguments have been exhausted.

- The inquiry process is aimed at determining whether the same substance has previously been registered or inquired about and facilitating contacts between previous and potential registrants. The objective is to achieve a better organisation of the data sharing discussions so that all registrants of a substance can comply with their data sharing and joint submission obligations. Although ECHA has a role in facilitating the communication between the registrants and potential registrants, in the inquiry process ECHA only checks the substance identity to the extent to be able to identify companies which have previously registered or inquired about the same substance. The inquiry does not allow an assessment of substance sameness to the level of detail.

- ECHA refers the parties to the Guidance, which contains generic advice on how to determine substance sameness while protecting confidential business information. In the case of non phase-in substances, [redacted] the EC numbers are more precisely limited than the EC numbers for substances belonging to the European Inventory of Existing Commercial Chemical Substances on the market ('EINECS'). While it is thus likely that the parties are indeed intending to register the same substance, the final responsibility for defining substance sameness rests with the Parties.[27]

[26] Please note that this section does not does not form the basis of ECHA's assessment of the efforts of the Parties in their negotiations. ECHA's assessment of the dispute is set out only in the section 'C. Assessment' of Annex I. 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.

[27] For more information on the establishment of substance sameness, please refer to Chapter 5 of the Guidance for identification and naming of substances under REACH and CLP.