[redacted]

Helsinki, 26 September 2019

The Claimant

[redacted]

Sent via REACH-IT

Copy to:
The Other Party

[redacted]

Represented by

[redacted]

Sent via REACH-IT and e-mail

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],

ECHA grants you permission to refer to the information you requested from the Existing Registrants and members of the Consortium of the Substance.

This decision is adopted under Articles 27(6) of Regulation (EC) No 1907/2006 ('REACH Regulation')[2] and Article 5 of the Commission Implementing Regulation (EU) 2016/9 on joint

[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] 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

[redacted]

submission of data and data-sharing in accordance with REACH ('Commission Implementing Regulation')[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, 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.

Minna Heikkilä[5]
Head of Legal Affairs

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 communication 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 efforts of the parties to reach an agreement (Article 5 of 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 a 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 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.

5. Moreover, making every effort entails negotiating towards reaching and agreement and then executing such agreement, without imposing new conditions which are not objectively justified and explained in the negotiations.

[redacted]

B. Summary of facts

1. This summary of facts is based on the documentary evidence submitted by the Claimant on 12 July 2019 and by the Other Party on 19 August 2019. For the purposes of this decision, every reference made to the Claimant and the Other Party refers to the parties which were negotiating the data according to the evidence provided.

2. On 23 January 2018, the Claimant contacted the Other Party on behalf of its client, asking for the price of the Letter of Access ('LoA') for a registration at [redacted] tonnes per year. It further asked whether there would be an option of joining the consortium on the substance, and what the costs would be in that case.

3. The Other Party presented the options available and corresponding prices. The parties agreed that the Claimant would join the consortium, and a contract was sent to the Claimant by the Other Party, and returned signed by the Claimant on 27 April 2018. On 7 May 2018, the Other Party sent an invoice.

4. On 7 June 2018, according to documentary evidence provided solely by the Other Party, the Other Party sent an e-mail to the Chief Executive Officer of the Claimant, while the rest of their correspondence was with the Claimant's consultant. This e-mail contained the token, as well as the technical file in IUCLID format and a list of studies.

5. On 9 July 2018, the Other Party wrote to the Claimant, explaining that it had been requested '*to have from all the members the* [redacted] *LoA, except if they are mentioned in the annex or if [the Claimant is] an affiliated member of the consortium*'. It directed the Claimant to contact the relevant [redacted] and indicated a consultant which could help with the process. The Other Party further asked the Claimant '*to make the necessary to obtain the* [redacted] *LoA*'.[6] On 25 July 2018, the Other Party sent to the Claimant '*the procedure document in order that [the Claimant has] the contact details of the* [redacted]', further stating that '*it is compulsory to have this LoA in order to be covered by all the tests*'.[7]

6. The Claimant reacted by noting that its client had '*signed the Consortium agreement in April 2018 and payed the fee* [redacted] *in May/June 2018*'. It asked whether, in addition, its client would have '*to sign a separate LoA document that must be first requested from the* [redacted]'. It understood that it did not have to pay for such separate LoA document, because it had already paid for the sharing of the data owned by [redacted].[8]

7. The Other Party replied the day after, informing the Claimant that it did not intervene in the process, and that the Claimant would have '*first to obtain the LoA* [redacted]'. Only after that, would the Other Party send the Claimant '*an invoice to be paid in order to receive the dossier (consortium member)*'.[9]

8. The Claimant contacted the [redacted] and asked for help from the consultant indicated by the Other Party.[10] On 31 August 2018, the Claimant informed the Other Party that it was '*still struggling with the* [redacted] *LOA issue*'. It asked which endpoints are covered

[6] E-mail from the Other Party; 9 July 2018.
[7] E-mail from the Other Party; 25 July 2018.
[8] E-mail from the Claimant; 25 July 2018.
[9] E-mail from the Other Party; 26 July 2018.
[10] E-mails from the Claimant to [redacted] contact point, 26 July and 6 August 2018; and to the consultant, 30 July 2018.

by the studies [redacted] and whether there are any other possibilities to cover them. It further expressed disappointment, stating it believed '*that the Consortium has the rights to the data needed in the registration*'.[11]

9. The Other Party directed the Claimant again to the Consultant, informing it that the '[redacted] *LOA covers animal tests. It is compulsory to have it*'. The Other Party added that the Claimant would have to '*select the information that is reliable, relevant and adequate*' for its registration, since the joint submission dossier will include all available studies.[12]

10. In February 2019, the Claimant wrote to the Other Party, asking whether there had been any change in the status of the information and its availability. It further asked whether the data would have any influence on the classification of the substance.[13] The Other Party stated that no changes had occurred with regard to the status, and asked the Claimant if it had contacted the consultant. It moreover informed the Claimant that '*an internal REACH Steering Committee [would take place] on April 9, 2019 and [it] will have more clarifications on the responsibilities of the co-registrants*'. In addition, the Other Party noted that there could be '*an additional test result available by the registrant that could replace the existing test in the* dossier'; it further stated that the Claimant could opt-out if it wished to '*deviate from the lead registrant dossier*'.[14]

11. On 29 March 2019, the Claimant replied it had not yet been able '*to find a solution to this* [redacted] *data issue*', and listed a number of points to be considered in the Steering Committee meeting. The following issues were raised: the Consultant indicated was not able to assist; [redacted] payments '*can be paid only* [redacted]', which creates '*an unreasonable obstacle to the payment*'; the '*additional test cost was not indicated when buying the LOA*', and its high price was unacceptable since it was not indicated before; '*the previous registrants were not required to buy additional LOA* [redacted]*, nor they have paid the* [redacted] *cost afterwards*', which makes the arrangement unfair, discriminatory and non-transparent.[15] The Other Party promised these issues would be considered in the meeting, reiterating however that it did '*not participate to the requirement for the* [redacted] *LoA*'.[16]

12. When the Claimant contacted the Other Party in order to receive an update on the meeting results,[17] the Other Party repeated the need for a [redacted] LoA and the instructions on how to obtain it.[18]

13. The Claimant asked, '*[a]s a last effort*', whether the Other Party could help with the [redacted] LoA issue, noting that the fact that previous registrants '*are covered*' and that no information had been given about this requirement before the payment was made '*raises a concern of unequal treatment*'. The Claimant stated it was '*open to any suggestions [the Other Party] can provide to help [it] forward with the registration as [it had] already paid the LoA but not received the token*'. It warned the Other Party it would be '*forced to initiate a dispute process with ECHA*'.[19]

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[11] E-mail from the Claimant; 31 August 2018
[12] E-mail from the Other Party; 31 August 2018.
[13] E-mail from the Claimant; 21 February 2019.
[14] E-mail from the Other Party; 21 February 2019.
[15] E-mail from the Claimant; 29 March 2019.
[16] E-mail from the Other Party; 4 April 2019.
[17] E-mail from the Claimant; 30 April 2019.
[18] E-mail from the Other Party; 6 May 2019.
[19] E-mail from the Claimant; 19 June 2019.

14. On 12 July 2019, 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.

15. On 12 September 2019, ECHA requested the Claimant to provide a proof that they paid the Other Party a share of the costs incurred by the Other Party ('proof of payment'). The Claimant did not inform ECHA of any agreement voluntarily reached by the parties. The Claimant provided the proof of payment on 19 September 2019 in the form of a scanned account statement.

C. Assessment

16. The negotiations between the parties swiftly led to an agreement at the end of April 2018, when a contract was signed between the parties, and the Claimant paid the requested compensation.

17. However, in July 2018, the Other Party informed the Claimant of a supplementary condition.[20] It indicated that, in order to register, the Claimant would need to purchase an additional Letter of Access from the relevant [redacted]. The Other Party moreover required a new payment '*in order to receive the dossier*'.[21] In February 2019, the Other Party indicated that there would also be further testing costs.[22]

18. Making every effort in negotiations requires transparency and fairness on the conditions imposed, as well as the equal treatment of all registrants, unless there are circumstances which can explain a different regime. Furthermore, making every effort entails negotiating openly and in good faith, as well as trying to understand and respond to the concerns of the counterparty, in order to achieve an agreement and allow the registration to proceed.

19. The Claimant was clear in its requests and prompt in its replies throughout the negotiations. It signed the data sharing and consortium agreement supplied by the Other Party, and paid the agreed compensation. When informed of the need for it, the Claimant tried to purchase the required additional Letter of Access, contacting both the consultant indicated and the contact point [redacted].[23] Faced with an inability to proceed, the Claimant came back to the Other Party in order to discuss alternatives.[24] It also raised concerns about discriminatory treatment between the different registrants, as well as the lack of transparency of a process which imposes new conditions after a contract has been signed.[25]

20. The Other Party, on the other hand, imposed a new condition of obtaining the agreement of the [redacted], after it had already agreed with the Claimant on data sharing and joining the consortium while it had not mentioned the need for such agreement earlier in the negotiations. When the Claimant could not obtain the LoA from [redacted] and turned to the Other Party for support it did not address the Claimant's concerns with respect to transparency and non-discrimination. This is aggravated by the fact that the Other Party had acted in a way which made the Claimant believe that it had the mandate to negotiate on and dispose of the data.

[20] E-mail from the Other Party; 9 July 2018.
[21] E-mail from the Other Party; 26 July 2018.
[22] E-mail from the Other Party; 21 February 2019.
[23] Supra footnote 10.
[24] E-mails from the Claimant; 31 August 2018, 21 February 2019, 19 June 2019.
[25] E-mail from the Claimant; 29 March 2019.

[redacted]

21. The unexplained introduction of an additional condition and the lack of replies to the Claimant's questions constitutes a failure on the Other Party's side to make every effort to find an agreement.

22. This finding is further confirmed by the e-mail sent by the Other Party to the Claimant's CEO with the technical dossier in the IUCLID format and the token.[26] In particular, the attachment to the e-mail contains the robust study summaries of the studies, for which the Other Party later required the Claimant to conclude an LoA with [redacted]. This further attests to the fact that an agreement had been signed and executed which covered all the data in the lead dossier which the Claimant needed, and that the Other Party unilaterally included an additional requirement in the negotiations subsequently.

D. Conclusion

23. The Claimant made every effort to reach an agreement on the sharing of information and provided a proof of payment of a share of the costs.

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

[26] ECHA notes that the e-mail sent to the Claimant's Chief Executive Officer was provided as evidence by the Other Party only. The e-mail was sent to this one e-mail address, and the normal interlocutors on the Claimant's side were not put in copy. It is unclear whether the information was at all received, since the Claimant alleges it paid the Letter of Access but never received a token.