[redacted]

Helsinki, 1 October 2018

The Claimant

[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 ('REACH Regulation')[1] and Article 5 of the Commission Implementing Regulation (EU) 2016/9

[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]

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, the parties must still make every effort to reach an agreement on the sharing of the information and costs related to the 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. 13 July 2018).

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

[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.

4. In particular, every effort means making efforts to be consistent in negotiations, respond to each other's requests in a timely manner and update each other regarding any developments, which might be relevant for moving the negotiations forward. Further, making every effort means to provide the necessary information for finding a common understanding on data and cost sharing, such as Letter of Access ('LoA') costs, the cost itemisation, or SIEF agreements without undue delay as set out in Article 2 of the Implementing Regulation 2016/9.

5. Further, Article 10(a) of the REACH regulation requires that '*the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised'* in a study summary and a robust study summary which are to be submitted *'for the purpose of registration'*. In practice, it means that the registrant who intends to submit a registration dossier needs to be a rightful data owner or have permission to refer through a LoA to the data for registration purposes. In order to be able to grant subsequent potential registrants permission to refer to the data of the third parties, the lead registrant needs to have the sub-licensing rights for this data.

[redacted]

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by both parties. On 13 July 2018, the Claimant submitted the evidence that covers the negotiations between the parties from February 2018 up to the dispute submission date, i.e. 13 July 2018. The Other Party provided the documentary evidence on 9 August 2018 covering the negotiations between the parties in 2015. ECHA notes that two different contact persons were conducting negotiations from the Claimant's side in 2015 and 2018.

6. On 3 September 2015, the Claimant contacted the SIEF formation facilitator asking for the contact information of the lead registrant for the Substance. After having received the lead registrant's name from the SIEF formation facilitator[5], on 8 September 2015, the Claimant informed the Other Party of their intention to register the Substances, inquired on how they could join the joint submission and requested a token.

7. The Other Party replied on the same day that in order to register the Substance of the Claimant's interest, the Claimant would need first to purchase a LoA for each of three individual constituents present in the Substance from a third party, named by the Other Party as owner of the data for these constituents. The Other Party requested the Claimant to provide: (i) a confirmation that the Claimant's Substance '*matches the sameness criteria*' of the Substance registered by the Other Party; (ii) a list of identified uses for the Substance; (iii) a pre-registration or inquiry number of the Claimant; (iv) information on the tonnage band; (v) the Claimant's company and contact details; (vi) *'[r]ecent excerpts of commercial register and of certificate of incorporation*' for *'legitimis[ing] the signing person as an official representative of [the Claimant's] company'*. The Other Party explained in detail the process of LoA provision.[6]

8. On 11 September 2015, the Claimant provided details concerning the substances sameness criteria and the pre-registration number, and confirmed the tonnage band for registration to be [redacted] tpa. They declared that they were ready to provide analytical reports and the list of identified uses later.

9. On 5 October 2015, the Claimant informed the Other Party that they were '*ready to pay the full amount'* for the LoA as if they were not the members of the Consortium and asked for the price to be paid, pointing out that they were in urgent need to register.

10. After the reminder by the Claimant[7], the Other Party replied on 13 October 2015 that on the contrary the fact that the Claimant was a member of the Consortium should '*help speeding up the process*'. Further, the Other Party highlighted that for the registration the Claimant needed *'a letter of access provided by [the third party – the data owner] for [the individual constituents (isomers) in the Substance] as the [Consortium's] dossier integrates data […] not owned by [the Consortium]. Data access […] has to be purchased by each registrant from [the third party – the data owner]'* and the Other Party '*strongly recommend[ed] contacting [the third party – the data owner] as also this [would] take time (contact attached)'*. The Other Party still needed the list of uses covered by the Claimant. They also stated that *'[a]fter this [was] resolved a LoA-contract can be compiled*' and that the Consortium's part of the LoA cost was estimated in the range of EUR [redacted]. They stated that the token could be granted '*if all steps described are passed*' in order '*to avoid premature sale of token leaving the co-registrant in the unfavourable condition not having a complete dossier'*.

[5] SIEF formation facilitator; 7 September 2015
[6] The Other Party; 8 September 2015
[7] The Claimant; 12 October 2015

[redacted]

11. On 16 October 2015, with reference to the Other Party and the Other Party in copy, the Claimant contacted the third party who was indicated by the Other Party as owner of the data used in the dossier for the Substance and enquired whether they could join the registration and what information they should provide.

12. Further, the Claimant sent a reminder to the data owner with the Other Party in copy on 22 October 2015.

13. On 17 December 2015 the Claimant's contact person informed the Other Party that they were leaving the Claimant's company and referred the Other Party to a new contact person in copy to the email *'regarding all the REACH matters'*.

14. On 12 February 2018, the new contact person on behalf of the Claimant (referred hereafter as the Claimant) contacted the Other Party and informed of their intention to register the Substance in [redacted] tonnage band. They wrote *'[h]ere are the details requested by [the Other Party]'*: (i) a confirmation *'that [their] substance matches the sameness criteria (or SIP)';* (ii) the list of uses covered by them; (iii) a pre-registration number; (iv) tonnage band to be [redacted] tpa; (v) the company and contact details; (vi) *'[r]ecent excerpts of commercial register and of certificate of incorporation'* of the Claimant.

15. On 15 February 2018, the Other Party replied that were *'currently investigating on [this] question and will get back to [the Claimant] really soon'.*

16. On 1 March, the Claimant sent a reminder to the Other Party stressing that *'the matter of high business[sic] priority for our company at a time'* and requested the LoA agreement and an invoice.

17. On 28 March, the Other Party wrote that *'[the Consortium] funding occurred through initial payments and by contributions received through the sale of Letters of Access'* was *'no longer sufficient to keep [the Consortium] alive',* therefore they requested an additional administrative fee of EUR [redacted] that would be *'sufficient to cover the 2018 and 2019 expenses'.*

18. The Claimant replied on 13 April 2018 with acknowledgment of the Other Party's concerns regarding funding and wrote that in order to decide whether to pay the received invoices, they needed *'itemization and justification of newly appeared administrative costs'* as they *'believe[d] that [they] have already payed administrative costs during the LoA purchase for substances [they have] registered'*. Finally, the Claimant noted that they had not received a reply regarding their request for the LoA for the Substance or SIEF agreement or invoices and that *'may lead to [their] products' existing supply disruption and can make impossible to sign new supply agreement for this product'*. They requested *'answers, argumentations and project of LoA purchase Agreement'.*

19. On 11 June 2018, the Other Party replied regarding the additional administrative fee pointing out that *'this was voted and approved during the last EC meeting held in January 2018'* and provided the link to the respective document online.

20. On 25 June 2018, the Claimant wrote to the Other Party that they *'still ha[d] not received argumented response to the letter dated 13.04.2018 on the issues concerning the purchase of LoA for [the Substance] for further registration, which in fact has a negative impact on our trade activities'.* They reminded the Other Party that *'[t]he inquires for LoA purchase were sent to [the other Party] in February and repeated in March and May 2018 but there were no responses'* and, with reference to the Implementing Regulation (EU) 2016/9 and the REACH regulation, that *'potential and the previous registrant(s) shall make every effort to reach an*

[redacted]

agreement on the sharing of the information requested by the potential registrant(s) with respect to Article 10'. Further, they highlighted that '*[w]hile [the Other Party was] answering on the invoices [the Other Party had] sent on other registrations but you're not answering on […] LoA purchase, your inactivity can be presumed as intentional blocking our free trade of [the Substance] on EU market*'. The Claimant provided again the details on the substance and the company earlier communicated in their initial request of 12 February 2018, expressing their hope '*that the problem can be sold without ECHA incorporation in it'*.

21. On 13 July 2018, the Claimant 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

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

23. The Claimant initially contacted the Other Party in 2015 and inquired how they could join the joint submission for the Substance. The Other Party promptly replied with the request for additional information regarding the company and the future registration, and wrote that at first the Claimant would need to obtain the data access for the individual constituents (isomers) present in the Substance and indicated the data owner for these individual constituents.[8] Later, in the email of 13 October 2015, the Other Party pointed out that the Claimant needed *'a letter of access provided by [the third party – the data owner] for the [individual constituents (isomers) present in the Substance] as the [Consortium's] dossier integrates data […] not owned by [the Consortium]. Data access […] has to be purchased by each registrant from [the third party – the data owner]* and they '*strongly recommend[ed] contacting [the third party – the data owner] as also this will take time (contact attached)'*. They also highlighted that '*[a]fter this [was] resolved a LoA-contract can be compiled*'. Thus, the Other Party explicitly indicated that they had used the data of the third party in their registration dossier and were not entitled to grant permission to refer to that part of the data; therefore, they referred the Claimant to the rightful data owner for obtaining the LoA for certain parts of data from the respective data owner. By doing so, the Other Party made efforts to move forward towards reaching an agreement on data sharing.

24. According to the information available to ECHA, the Claimant contacted the data owner regarding the LoA for the needed data on 16 October 2015. ECHA has no further information regarding the Claimant's negotiations with the data owner, as the Claimant has not submitted any correspondence related to the year 2015 nor updated the Other Party about any further developments of their negotiations with the data owner. More specifically, there is no indication that the Other Party would have been aware of a data-sharing agreement concluded between the Claimant and the data owner, nor whether the Claimant had intentions to continue with their registration for the Substance between December 2015 and February 2018.

25. In February 2018, the Claimant contacted the Other Party and informed them of their intention to register the Substance in [redacted] tonnage band. After a two-year interruption in the negotiations, the Claimant asked for the LoA for the Substance and in the same juncture provided the Other Party with some additional information requested by the Other Party in 2015, e.g. '*[r]ecent excerpts of commercial register and of certificate of incorporation'.* The Other Party responded to the Claimant's request with one holding reply and by sending communications regarding the Consortium's additional administrative fee, however, they did

[8] The Other Party; 8 September 2015

[redacted]

not provide an answer to the Claimant's reminders related to the LoA for the Substance.

26. However, as outlined in section A., the potential registrant shall be provided with all necessary information regarding the LoA costs, such as the itemisation and justifications of the relevant costs upon request and without undue delay to allow the potential registrant to assess whether the proposed cost sharing is fair, transparent and non-discriminatory. Given the need to obtain the LoA for the individual constituents (isomers) present in the Substance from the third party data owner, as was communicated to the Claimant in 2015, the Other Party could have again raised this matter to request clarification whether the Claimant had found an agreement with that third party data owner. The Other Party also could have referred the Claimant to the data owner once more, if that step was still pre-requisite for the conclusion of the data-sharing negotiations between the Claimant and the Other Party. The lack of reply from the Other Party to the latest queries of the Claimant therefore indicates a lack of effort to reach an agreement by the Other Party.

27. On the other hand, ECHA takes note that the Claimant had repeatedly been made aware of the fact that they needed to obtain the LoA for the individual constituents (isomers) present in the Substance from the third party data owner in 2015. However, the Claimant did not pursue the negotiations for over 2 years by not contacting the Other Party until 2018, and by not informing them about the situation concerning the access to the data held by the third party data owner, thereby failing to make every effort to reach an agreement on data sharing. By merely insisting on receiving information regarding the LoA costs from the Other Party, and by not following-up on or providing information about a potential agreement with the third party data owner, the Claimant did not advance the negotiations and therefore failed to make every effort.

Conclusion

28. ECHA takes into consideration the entire negotiations between the parties and all the information available to ECHA regarding the Other Party's registration strategy and that they were not entitled to grant permission to refer to potential registrants, of which they informed the Claimant already in 2015. Against this background, on balance of effort, ECHA concludes that the Other Party's effort to progress negotiations undertaken at the early stage of the negotiations outweighs the fact that they could have made more effort during the second stage of the negotiations in 2018. More importantly, however, ECHA also observes that the Claimant failed to make every effort by not contacting the third party data owner and by not informing the Other Party about a potential progress of their negotiations with the third party data owner.

29. Therefore, ECHA does not grant the Claimant access to the joint submission nor permission to refer to the studies.

[redacted]

Annex II: ADVICE AND FURTHER OBSERVATIONS[9]

- The Parties should continue the negotiations aiming to reach an agreement on the access to the joint submission and on the sharing of information as a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would.

- If a potential registrant aims to be part of a joint submission but does not agree with a proposed data and cost sharing model, the potential registrant should negotiate constructively with the existing registrant(s) the basis of the chosen model in terms of transparency, fairness and non-discrimination.

- To achieve a fair, transparent and non-discriminatory agreement on the sharing of the data and their costs, as well as on forming a joint submission, it is crucial that the parties can find a mutually agreed basis of the costs. This is the purpose of the itemisation requirement imposed by the Implementing Regulation (EU) 2016/9, as such an itemisation allows to identify the relevant costs and to objectively challenge them if needed. Therefore, ECHA recommends that negotiations between the parties are based on such an objective itemisation rather than on approximate costs without any justifications or objective basis.

- While the cost calculation model that is in place may be complex, the existing registrant(s) are required to balance the need for administrative efficiency with their transparency obligation in data sharing negotiations.

[9] 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.