[redacted]

Helsinki, 14 May 2018

The Claimant

[redacted][1]

Copy to:
The Other Party

[redacted]

Represented by

[redacted]

Decision number: [redacted]
Dispute reference number: [redacted]
Name of the Registered Substance: [redacted]
EC number of the Registered Substance: [redacted]

DECISION ON A DISPUTE RELATED TO THE ACCESS TO A JOINT SUBMISSION AND THE SHARING OF DATA

a. Decision

ECHA grants you the permission to refer to the information you requested from the Existing Registrant of the Registered Substance and access to the joint submission.

This decision is adopted under Articles 30(3) and 11 of Regulation (EC) No 1907/2006 ('REACH Regulation')[2] and Article 5 of the Commission Implementing Regulation (EU) 2016/9

[1] Acting as a third party representative pursuant to Article 4 of Regulation (EC) No 1907/2006. ECHA notes that where a potential registrant has made use of a third party representative according to Article 4 of the Regulation, the rights and obligations granted by the present decision solely apply to the potential registrant.

[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.

[redacted]

on joint submission of data and data-sharing in accordance with REACH ('Implementing Regulation 2016/9')[3].

The reasons of this decision are set out in Annex I. The list of studies to which ECHA grants you permission to refer along with copies of (robust) study summaries can be found in Annex 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 of 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 30(3) of the 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(s) is made available to you.

Furthermore, please note that with the present decision ECHA only gives you a permission to refer to studies involving tests on vertebrate animals. However, the obligation of a SIEF member to share data on request by another SIEF member also extends to data not related to vertebrate animals.

ECHA will inform the competent national enforcement authorities of the present decision. The national enforcement authorities may take enforcement actions according to Articles 30(6) and 126 of the REACH Regulation.

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 of 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

[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.

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Annex I: REASONS OF 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 a 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 the 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 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. 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 that upon request of a potential registrant, the existing registrants need to provide information on the cost of the Letter of Access to the data ('LoA') and access to the joint submission. Such information is crucial to enable meaningful data sharing negotiations, as a potential registrant is not in a position to objectively assess and understand the data and the corresponding costs otherwise and whether the requested compensation is fair, transparent and non-discriminatory, as well as to assess the relevance of the jointly submitted data.

5. Further, making every effort also requires that parties express clearly and transparently their needs and constraints, such as their registration schedule. It also means that the parties have to take into account the constraints expressed by their negotiating partner and respect the timelines they communicate to them.

B. Summary of facts

6. This summary of facts is based on the documentary evidence submitted by the Claimant together with their dispute claim on 2 March 2018. On 22 March 2018, the Other Party provided to ECHA documentary evidence consisting of an email and its attachments sent by the Other Party to the Claimant on 21 March 2018. This email and its attachments post-date the submission of the dispute claim to ECHA, i.e. 2 March 2018. Therefore, ECHA did not take these into account in its assessment of the dispute.

7. On 8 June 2017, the Claimant initiated the negotiations, indicating their intention to register the substance with CAS number [redacted] ('Substance [redacted]'). The Claimant expressed interest in potential read-across data sharing on a substance registered by the Other Party that they considered similar to their own ([redacted]), and requested the cost for a LoA to the

[redacted]

data of the similar substance ([redacted]).[6] In their reply, the Other Party indicated that they are acting as a service provider for the lead registrant of the similar substance (i.e. [redacted]) and requested further information on the identity of the Claimant's substance to assess the suitability of a read-across approach.[7]

8. After some clarifications[8], the Other Party explained to the Claimant that the Substance [redacted] had been registered by the Other Party together with another similar substance ([redacted]) as part of EC number [redacted] ([redacted], hereinafter the 'Registered Substance'). In case the Claimant would want to register the Substance [redacted], the Other Party indicated that the data for the Registered Substance would be more suitable for read-across. The Other Party indicated that they would provide feedback on the comparison of the Claimant's substance with the Registered Substance once the Claimant would have provided information on the identity of their substance.[9]

9. On the same day, the Claimant indicated that they will provide the information on the identity of their substance. They also asked for the LoA cost for the Registered Substance in the tonnage band [redacted].[10] The Other Party responded on the same date that the registration was only 6 months old and, since they had not yet received interest from other registrants, the LoA cost was not ready. Consequently, they indicated that they '*need[ed] something like 6-8 weeks […] before the price is ready*'.[11]

10. The Claimant again contacted the Other Party on 10 July 2017 asking for an approximate cost with '*e.g. an approximate upper and lower estimate*'[12] of the LoA for the Registered Substance in order to plan the Claimant's budget. On the same day, the Other Party responded that they would provide an approximate cost as soon as this information was available, expecting this to happen '*sometime next week*'. In this message and in the following ones in the negotiations, the Other Party did not repeat their request for information on the identity of the Claimant's substance.[13]

11. The Claimant sent a reminder to the Other Party on 6 October 2017 on their request to obtain information on the LoA cost for the Registered Substance.[14] The Other Party responded on 9 October 2017, apologizing for the delay in contact and stated that they '*must check for some missing information and [they] will make sure that [the Claimant] will receive a reply in the next few days*'.[15]

12. The Claimant again contacted the Other Party on 9 November 2017 and stated that they had '*still not received any information regarding the LoA cost for [the Registered Substance] in the [redacted] band*' and asked if the Other Party could '*let [them] know as soon as possible when the costs will be finalised and the reasons for the delay*'.[16]

13. The Claimant contacted the Other Party for the last time on 12 February 2018 and asked the Other Party to respond to them '*by 16th of February 2018 with information on the data sharing terms and conditions as well as the related costs*'. The Claimant further stated that since they '*need to proceed with [their] registration urgently, if [they] do not receive a response by the above date [they] will have no choice but to lodge a data sharing dispute with ECHA in order*

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[6] Claimant; 8 June 2017.
[7] Other Party; 17 June 2017
[8] Claimant; 20 June 2017
[9] Other Party; 26 June 2017
[10] Claimant; 26 June 2017
[11] Other Party; 26 June 2017
[12] Claimant; 10 July 2017
[13] Other Party; 10 July 2017
[14] Claimant; 06 October 2017.
[15] Other Party; 09 October 2017
[16] Claimant; 09 November 2017

[redacted]

to access the joint submission."[17]

14. On 2 March 2018, the Claimant submitted a claim under Article 30 of the REACH Regulation concerning the failure to reach an agreement with the Other Party on the access to the joint submission and the sharing of information for the Registered Substance.

C. Assessment

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

14. The Claimant repeatedly requested the cost of the LoA for the tonnage band [redacted] for the Registered Substance. They accepted the initial timeline proposed by the Other Party and sent repeated reminders throughout the negotiations when the Other Party did not provide the requested information. In order to obtain an indication on the costs despite the time requested by the Other Party to gather the final LoA cost, the Claimant asked for an estimation of the LoA cost. The Claimant also indicated their need to plan their budget based on the LoA cost and their urgency to register their substance. By doing so, the Claimant made effort to get the information they needed and to explain their situation.

15. On the other hand, the Other Party did not provide any information on the LoA cost by the time the dispute was filed, i.e. almost 8 months after the initial request from the Claimant for the LoA cost for the Registered Substance. The provision of costs related to data and administration is the starting point for any data sharing negotiations. The existing registrant needs to make every effort to provide information to a potential registrant to allow them to understand the costs with respect to time constraints relating to registration. Making every effort in the negotiations entails that an existing registrant needs to take into account the urgency for the potential registrant to register, and not delay sending vital information, such as the cost of LoA. By not providing to the Claimant any information on the cost (including an estimation), the Other Party showed a failure to make efforts to find an agreement.

16. ECHA acknowledges that putting together LoA cost may take time. However, making every effort requires existing registrant(s) to justify the delays they encounter and to provide clear timelines to the potential registrant(s). At the beginning of the negotiations, the Other Party attempted to explain why they were not able to provide the LoA cost upon the first request, *i.e.* that the registration had been submitted only 6 months earlier and had not received interest from other potential registrants yet. However, all the following delays remained unjustified. Moreover, the Other Party communicated some timelines by which the LoA cost or an estimation of cost would be ready (*'6-8 weeks'*, *'sometime next week'*, *'in the next few days'*). However, the Other Party did not respect any of these communicated timelines. By providing neither justifications for the encountered delay nor reliable timelines by which the Claimant could expect to receive the LoA cost, the Other Party showed a failure to make efforts to find an agreement.

17. Therefore, by not providing any information on the LoA cost despite the several reminders sent by the Claimant, the Other Party prevented meaningful negotiations from starting and thus did not make every effort to find an agreement with the Claimant.

18. In light of the above, the Claimant could consider that the negotiations with the Other Party would not progress on time in view of their urgent need to register and they filed the dispute to ECHA as a measure of last resort.

19. Against this background, ECHA notes that it does not appear from the negotiations that the Claimant provided the information initially requested by the Other Party on the identity of the Claimant's substance. However, the Other Party did not reiterate this request after their

[17] Claimant; 12 February 2018

[redacted]

message of 26 June 2017. Therefore, it clearly appears that the negotiations were delayed by the absence of provision by the Other Party of information or estimation on the LoA cost, and not by the Other Party's request for information on the identity of the substance.

Conclusion

24. The Claimant made every effort to reach an agreement on the access to the joint submission and the sharing of information in a fair, transparent and non-discriminatory way, while the Other Party did not.

25. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the information involving studies on vertebrate animals requested from the Other Party, as listed in Annex II to the present decision.