[redacted]

Helsinki, 24 July 2018

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

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 ACCESS TO A JOINT SUBMISSION AND THE SHARING OF DATA

A. Decision

ECHA grants you permission to refer to the information you requested from the Existing Registrant of the 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')[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. 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.

[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]

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

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 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 or reports (if applicable) are made available to you.

Furthermore, please note that with the present decision ECHA gives you a permission to refer to studies only 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 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.

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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 that upon request of a potential registrant, under Article 30 of REACH and Articles 2 and 4 of Commission Implementing Regulation, the existing registrants need to provide proof of the cost of any study or any study related activity. Such information is crucial to enable meaningful data-sharing negotiations, as otherwise, a potential registrant is not in a position to objectively assess and understand the data and the corresponding costs. Information on the cost of the Letter of Access ('LoA') to the data and access to the joint submission enables the potential registrant to assess whether the requested compensation is fair, transparent and non-discriminatory, as well as to assess the relevance of the jointly submitted data.

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant, together with their dispute claim, on 8 May 2018, and on the documentary evidence submitted by the Other Party on 29 May 2018.

6. The discussion between the parties started on 22 March 2018, when the Claimant sent an email to the lead registrant of the Substance. The Claimant informed the Other Party about their willingness to join the Joint Submission for the Substance and they asked for a Letter of Access ('the LoA') agreement. On the following day, the Other Party informed the Claimant that their request was forwarded to the Other Party's consultant. Upon receiving no reply to their initial email, the Claimant sent reminders on 4 April and 24 April 2018 to the Other Party. In the latter email the Claimant also stated that if they *'do not receive any feedback within this week* [they] *will submit* [their] *own dossier with help of ECHA'*.

[redacted]

7. On 24 April 2018, the Other Party sent the Claimant a SIEF Agreement and informed the Claimant that 'the *cost of the LoA is* [redacted]*€, taking into account that* [the Claimant] *shall be reimbursed in case more companies finally join the registration*'. On the same day, the Claimant replied that they '*assume that* [the cost] *is valid for* [redacted] *and not for* [redacted]' and that the Claimant '*is willing to buy*'. Nonetheless, the Claimant asked the Other Party to provide information, '*according to the Guidance on Data-Sharing*', how the cost was calculated.

8. On 24 April 2018, The Other Party informed the Claimant that in order to provide that information, the parties '*must sign a NDA* [non-disclosure agreement] *since* [the Other Party is] *not allowed to distribute that information*', and that '*this will delay the procedure about 2 or 3 weeks*'. On the same day, the Claimant replied to the Other Party's email by stating, that '*in this case, we assume our registration obligation cannot be fulfilled and therefore will go for a complete opt-out and register with our own data*'. The Claimant also stated that '[b]*ased on the latest decision of ECHA and the BoA you are obligated to provide us the* [token] *for the registration without further delay and payment*'. In addition to the token, the Claimant also requested an opt-out agreement and a detailed breakdown of the administrative costs to be provided '*within the next 5 working days*'. The Claimant stated that upon a failure to provide the requested information, the Claimant would request the token from ECHA.

9. On 24 April 2018, following the Claimant's request for an opt-out token, the Other Party asked whether the Claimant is intending to register in the tonnage band of [redacted]. On the same day, the Claimant confirmed that their tonnage band is [redacted] and requested for the new cost to be provided. On the same day, the Other Party informed the Claimant that the LoA cost for the tonnage band of [redacted] is [redacted]*€,* [redacted]. The Other Party pointed out that the lead registrant is also the only registrant for the substance, therefore '*the cost has been estimated considering* [redacted] *more coregistrant, being* [the Claimant] *the only one interested in the tonnage range* [redacted]. They stated that the cost would be recalculated and reimbursement applied in case more registrants join the registration.

10. On 25 April 2018, the Claimant informed the Other Party, that they find the costs '*incredibl*[y] *high compared to the content of studies included*'. They confirmed that they wanted to opt-out and asked the Other Party to proceed with their request. The Other Party replied on the same day by informing the Claimant that [redacted] *studies included in Annex* [redacted] *had all been performed and this SIEF had been running for 7 years*'. They also asked why the Claimant considers the estimated cost for the LoA as '*incredibly high*'.

11. On 25 April 2018, the Claimant explained that after reviewing the dissemination file they '*came to conclusion that no relevant study performed on* [the substance] *is available in the dossier*'. The Claimant stated that for this reason, they think that the LoA cost is unjustifiable '*until* [the Claimant] *received a derivation of the cost according to the Guidance on Data-sharing*'. On the same day, the Other Party responded by informing the Claimant which studies have been performed, and stated that some studies relevant to Annex [redacted] have not been charged from the Claimant along with the literature data.

12. On 8 May, the Claimant informed the Other Party about their decision to file a data-sharing dispute.

13. On 8 May 2018, the Claimant submitted a claim under Article 30 of the REACH Regulation, concerning the failure to reach an agreement on access to the joint submission and the sharing of information with the Other Party.

C. Assessment

14. As explained in section A., ECHA assesses the efforts made by the parties in the

[redacted]

negotiations that were outlined in section B.

15. Making every effort means that an existing registrant needs to address requests by a potential registrant to reach a data-sharing agreement in a fair, transparent and non-discriminatory manner. 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. Making every effort in the negotiations entails that, an existing registrant takes into account the urgency for the potential registrant to register in light of an approaching registration deadline, and do not delay sending relevant information such as a cost breakdown.

16. The Claimant made several efforts to receive the requested information from the Other Party. The Claimant sent two reminders dated 4 April and 24 April 2018, having not received reply from the Other Party after their initial inquiry. Furthermore, after receiving information about a possible delay in providing the LOA cost that would be caused by signing the NDA, the Claimant considered an opt-out as an option to proceed forward with the negotiations. In this context, the Claimant also emphasized their willingness to pay administrative costs related to the opt-out. In addition, during the extensive negotiations that took place within two days, the Claimant requested two times[5] the detailed cost breakdown of the LoA, and once[6] the opt-out related administrative costs breakdown. Finally, they tried to justify their statements regarding the cost by reviewing openly accessible information from the ECHA dissemination page.

17. The Other Party made an effort to comment on the Claimant's statement regarding the costs by informing the Claimant, which studies had been performed. However, ECHA notes that under the Implementing Regulation 2016/9, the existing registrant has a responsibility to make every effort to provide all evidence, without undue delay, of the relevant costs to a potential registrant so that the potential registrant can make an informed assessment as to whether the costs are fair. The Other Party requested an NDA to be signed before provision of a cost breakdown, informing the Claimant, that it would delay the registration procedure up to three weeks.

18. The Claimant raised concerns that they would not be able to complete their registration in a timely manner and as a result, would breach their regulatory obligations, namely to submitted a registration by the 31 May 2018 registration deadline. Therefore, they requested the Other Party to provide them with an opt-out token. However, the Other Party did not address this request. As confirmed in the Board of Appeal decision A-011-2017, the lead registrant has an obligation to provide a token for a potential registrant allowing them to join the joint submission by submitting their own data.[7] ECHA notes, that by not providing the requested token and by ignoring the opt-out request, the Other Party denied the Claimant of a possibility to proceed with their registration.

19. Moreover, by also not providing any information on the requested cost breakdown, the Other Party prevented meaningful negotiations from advancing. ECHA notes, that by not addressing either of the requests from the Claimant, the Other Party effectively blocked the Claimant from submitting their registration on time. Consequently, by not providing the cost breakdown, combined with not providing the token and ignoring the opt-out request, the Other Party did not make every effort to find an agreement with the Claimant.

20. In light of the above, the Claimant could not have done any more efforts to reach an agreement with the Other Party. By sending reminders to the Other Party, by justifying their requests and by suggesting to opt-out while still agreeing to continue discussing the

[5] The Claimant, 24 April 2018 and 25 April 2018

[6] The Claimant, 24 April 2018

[7] Decision of the Board of Appeal of the European Chemicals Agency, A-011-2017, 23 March 2018, para 40.

[redacted]

joint submission, shows that the Claimant made every effort to reach an agreement.

D. Conclusion

21. The Claimant made every effort to reach an agreement on access to the joint submission and the sharing of information, whereas the Other Party failed to make such effort.

22. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies specified in Annex II.