[redacted]

Helsinki, 26 November 2018

The Claimant

[redacted]

Represented by

[redacted]

Copy to:
The Other Party

[redacted]

Decision number: [redacted]
Dispute reference number:
Name of the substance (the 'Substance'):
EC number of the Substance:

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

[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]

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.

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

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[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 and 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 the 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 providing potential registrants with all relevant information necessary for moving forward with the negotiations in a prompt manner. According to Article 2(1) of Implementing Regulation 2016/9, a data-sharing agreement - including inter alia, the itemisation for all relevant costs and a cost-sharing model with a reimbursement mechanism must be provided without undue delay. Article 30(1) of REACH obliges an existing registrant to provide the information at the latest after one month. When the itemisation and justification of costs are provided, potential registrants are able to assess whether the requested compensation is fair, transparent and non-discriminatory. Any delays need to be justified, and a delay cannot in any case be justified if it results in obstructing potential registrants that have contacted the other company in a timely manner from registering.

[redacted]

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 6 September 2018 and by the Other Party on 28 September 2018. The documentary evidence, which the Claimant provided, covers the negotiations between 4 August 2016 and the dispute submission date 6 September 2018. The Other Party provided documentary evidence from 10 April 2017 until the date of submission of the dispute.

6. On 4 August 2016, the Claimant contacted the Other Party and communicated their interest in *'a Member registration'* for the Substance. They wrote with reference to the ECHA webpage that they noticed that the Other Party had registered the [redacted] with EC number [redacted] and requested the substance identity profile (from hereinafter referred to as 'SIP') for [redacted] with EC number [redacted] to understand whether that registration would cover also the Substance, [redacted] with EC number [redacted] (referred to as '[redacted] or 'the Substance'). The Other Party provided the SIP on 16 September 2016 stating that it was under revision. The Claimant then tried to obtain information on when the revised SIP would be ready by sending several reminders[5] as well as speaking with the Other Party on the phone[6].

7. On 5 April 2017, the Claimant wrote an email to the Other Party and said that they had received the Other Party's email address from their [redacted] colleagues in [redacted] and were contacting them in *'urgent need for support'*. The Claimant further stated that [redacted], as the EU-based Only Representative of both [redacted] Companies, was under the obligation to register [redacted] under the REACH Regulation. The Claimant also informed that [redacted] had engaged [redacted] as external support, as they *'urgently need[ed] access to the updated SIP so that [they could] confirm the possibility of co-registration'* and that *'[they would] appreciate [the Other Party's] support in bringing forward [their] request and complete it as soon as possible'*.

8. On 7 April 2017, the Other Party offered that they could act as the Only Representative for their *'customers who use [redacted] and/or [redacted] in [their] products'* and added that if the Claimant *'still would rather register [redacted] under [their] own registration, that [was] another process which could get expensive'* and would require purchasing the Letter of Access ('LoA'). The Claimant replied to the Other Party on 10 April 2017 that they had *'the intention to register on [their] own'*. However, before that, they would still have liked to verify their SIP with the Other Party's revised SIP for [redacted] with EC number [redacted], which had not yet been available, *'thus preventing [them] to proceed with the preparation of [their] own registration'* for the Substance. The Other Party provided the revised SIP for the [redacted] with EC number [redacted] to the Claimant on 17 April 2017.

9. On 28 April 2017, the Claimant communicated to the Other Party that they had received a SIEF survey from a third company *'with respect to [the third party's] intention to register [redacted] ([redacted]) as the Lead'*. The Claimant stated that they *'want[ed] to co-register and [they] would like to know, if it [was] possible to register with [the Other Party]'*. The parties then agreed to have a teleconference and also discussed a possible downstream user agreement between them. On 6 July 2017, the Claimant inquired whether *'there [was] a new update on the registration of [the Substance]'*. On 18 July 2017, the Claimant asked for a call to be updated *'about […] the registration process of* [redacted]

10. On 11 August 2017, the Other Party informed the Claimant that, while updating their registration dossier for [redacted] with EC number [redacted], they decided *'to register [the Substance] as a separate substance with a separate dossier'* and they *'[were] volunteering to become a SIEF facilitator and lead registrant for [the Substance]'*. They

[5] Claimant; 19 October 2016, 18 November 2016, 15 December 2016, 17 January 2017, 23 January 2017, 14 March 2017, 5 April 2017, 10 April 2017, 11 April 2017

[6] Claimant; 23 February 2017

requested the Claimant to complete a SIEF survey for the Substance and acknowledge the Other Party's lead role by responding via email by 25 August 2017.

11. On 14 August 2017, the Claimant answered the SIEF survey, indicated their intention to register with the tonnage band of [redacted] and that they did not own any data for the Substance. They also confirmed that *'[a]s [the Other Party … knew they] would also follow the registration as a downstream user of [the Other Party] besides the approach of a Co-Registration but [were] waiting for the agreement'*.

12. On 12 October 2017, the Claimant asked the Other Party to have a short call *'about […] the progress with* [redacted] to be held on 17 October 2017.

13. On 14 November 2017, the Claimant asked for *'news on the change of the lead role'* from the third party to the Other Party[7].

14. On 6 December 2017, the Claimant again asked for *'an update about the progress with the registration of [the Substance]'*. On 8 January 2018, the Claimant repeated the same question, asked also if the Other Party had now the lead role instead of the third party and suggested a time for a short phone call with the Other Party.

15. On 2 February 2018, the Claimant expressed their worry for being unable to register the Substance *'until the deadline in May'* and again requested for *'an update about the registration and also the SIEF work'*. Further, they wrote that they had tried to call the Other Party *'already several times but could not reach [them]'* and asked for *'a time next week for a call'*.

16. On 4 May 2018, the Claimant wrote that they *'[had] informed ECHA and […] applied for DCG solution[8]'*. They also enquired if the Other Party had made *'any progress with the discussion with [the current lead]'* on whether the latter *'[was] willing to hand over the lead position'* and requested a response *'until middle of next week'*.

17. On 17 May 2018, the Claimant communicated to the Other Party that ECHA had informed them in a call that their DCG-application was rejected *'because this problem need[ed] to be solved by the current lead, which [was] obligated to submit a complete dossier'* and that if the current lead did *'not submit a lead dossier successfully within the deadline (until May 31, 2018), all* [redacted] *EU imports [would] have to be stopped'*. The Claimant also stated that ECHA had advised them to ask the current official lead *'to provide the co-registration information such as token, joint submission group name and if available the LoA costs, which [the Claimant] had already ask[ed] for of […] May 17, 2018[…]. [The Claimant] propose[d the Other Party to] do the same'*. In addition, the Claimant asked the Other Party to answer *'undelayed'* to the new lead role-clarifying SIEF survey that the Other Party *'should have received […] already'*. The Claimant enquired as well whether if the Other Party *'[became] the new chosen lead, [they would] be prepared to successfully submit [their] lead dossier (*[redacted] *within the deadline and probably with a more time given from ECHA […or had they] decided to […] not want to be the lead of the substance and stop the EU imports* [redacted] *'*. The Claimant further asked whether the Other Party would *'be able to provide [them] the token, joint submission group name and if available the LoA costs undelayed'*. Finally, they requested *'the results of [the Other Party's] SIEF survey […]'*.

18. On 25 May 2018, the Claimant informed the Other Party that they had received from ECHA an official letter assigning the Other Party as the lead registrant for the Substance and recommending the Other Party *'to provide the token and JS name to the co-registrants immediately to assure an in-time co-registration'*. The Claimant asked the Other Party to

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[7] [redacted].

[8] Directors' Contact Group; see also https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues

[redacted]

'confirm that the token [would] be sent at the latest Monday 27th of May' and whether [redacted]*'*.

19. On 14 June 2018, the Claimant asked the Other Party *'how [the Claimant could] co-register* [redacted] and requested *'the SIEF Agreement and costs'*, asking the Other Party to *'answer to [their] email this time'*.

20. On 20 June 2018, the Claimant stated that they had *'just seen that the submission of [the Other Party's] lead dossier [was] finally completed'* and asked for *'the LoA costs (& calculation)'*, [redacted] and if they *'[were going to] send out a SIEF information to the complete SIEF'*. The Claimant also wrote that they *'would like to submit [their] Co-dossier as soon as possible'*.

21. On 10 July 2018, the Claimant repeated their wish to *'co-register the substance'* and requested again for *'the SIEF Agreement, the LoA costs (& calculation) and information if* [redacted] They also asked whether the Other Party intended to *'send out a SIEF information that the complete SIEF [knew] that [they were] the lead registrant'*. The Claimant requested for a reply by 27 July 2018 and stated that *'[o]therwise, [they were] in the need to contact ECHA'*.

22. On 27 July 2018, the Claimant communicated to the Other Party that they had had a meeting the same day with their consultant and *'apparently had to initiate communication with ECHA that [the Claimant would] not be able to co-register due to a lack of info from [the Other Party]'*. They also stated that a *'response [was] necessary for [them] to continue business in Europe'*.

23. On 27 July 2017, the Other Party replied to the Claimant that they *'should have the information needed completed by Monday July 30, or Tuesday July 31 at the latest'*.

24. On 15 and 22 August 2018, the Claimant communicated to the Other Party their intention to contact ECHA since they had not received new information from the Other Party.

25. On 22 August 2018, the Other Party replied that they *'should be completed with the SIEF Agreement and LoA costs by early next week. [They had] needed some assistance from [their] consulting firm on study costs and LoA calculations'* and apologised for the delay. The Claimant replied that they *'they wished to have no delays anymore'* and that *'since 1st of June [they had] stopped the import of* [redacted] *into the EU and* [redacted]. They repeated their request for *'the relevant information to successfully co-register* [redacted] and further wrote that if they did *'not get all information from above or only a part'* by 28 August they would inform ECHA the following week. The Other Party sent the requested SIEF agreement, LoA costs and [redacted] to the Claimant on 28 August 2018.

26. On 31 August 2018, the Claimant sent their *'comments and corrections'* to the SIEF Agreement and LoA costs stating that there were *'some important open issues like the cost sharing,* [redacted] *Affiliates, study rights etc.'*. They requested a *'reply to [their] comments and to accept [their] corrections until 04th of September'* and hoped for an answer to all of their *'questions because [they] want[ed] to avoid several rounds of comment sending since [they] really need[ed] to register urgently'*.

27. On 6 September 2018, the Claimant communicated to the Other Party that since they again had *'not heard back from [the Other Party they had] no other choice but to submit [...] data sharing dispute to ECHA'*.

28. On 6 September 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

[redacted]

and the sharing of information with the Other Party.

C. Assessment

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

30. ECHA notes that throughout the negotiations since 2016, the Claimant repeatedly sent requests and regular reminders to the Other Party. The Other Party did not answer to the Claimant promptly, or replied after several reminders and after the Claimant had communicated their intention to contact ECHA.

31. Furthermore, during the negotiations, the Claimant was proactive and followed up on the Other Party's registration status. The Claimant demonstrated their efforts to register by the registration deadline by persistently sending emails despite the lack of a response from the Other Party. In addition to the emails, the Claimant also tried to contact the Other Party by phone. By doing so, the Claimant showed efforts to find an agreement with the Other Party.

32. ECHA acknowledges that it was apparent to the Other Party that the Claimant was under a regulatory obligation to register the Substance by the registration deadline 31 May 2018 and needed access to the data and the joint submission as soon as possible. The Other Party should have considered the circumstances of the registration deadline and lived up to their obligation to provide the data sharing agreement according to Article 2 of Regulation 2016/9 without undue delay. The Other Party did also not inform the Claimant that they had submitted their lead dossier for the Substance[9].

33. The Other Party provided the LoA cost proposal several months and reminders after the Claimant had initially expressed their intention to register and requested information on the LoA. ECHA therefore considers that the Other Party failed to address the Claimant's urgency to register by the deadline in May, even though the Claimant had emphasized this fact clearly and repeatedly, and thus the Other Party did not show efforts to find an agreement.

34. ECHA recognises that the Claimant requested the Other Party to answer to the Claimant's counterproposal within only a few days, and that the Claimant launched the dispute two days after they had not received a reply by the set deadline. However, in view of the Claimant's urgency to register and considering the Other Party's lack of prompt replies previously, ECHA considers that the Claimant justifiably launched the dispute as a last resort. Accordingly, the Claimant complied with their obligation to make every effort to reach an agreement on the conditions on data sharing and the related costs in a transparent way as required by REACH and the Commission Implementing Regulation.

D. Conclusion

35. Based on the above, ECHA concludes that the Claimant made every effort to find an agreement in the negotiations.

36. By not promptly providing the LoA costs and cost itemisation and not addressing the Claimant's concerns regarding the registration deadline, the Other Party did not make every effort to reach an agreement.

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

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[9] Claimant; 20 June 2018