[redacted]

Helsinki, 10 January 2019

The Claimant

[redacted]

Copy to:
The Other Party

[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 finds that you made every effort to find an agreement on data sharing and grants you permission to refer to the studies involving testing on vertebrate animals you requested from the Other Party and access to the joint submission.

Once the studies have been submitted by the Other Party, ECHA will make a copy of the robust study summaries available to you. Then the permission to refer to the studies will take effect and ECHA may provide technical instructions on how to prepare your dossier. Your submission will remain suspended from further assessment until then.

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 endpoints, for which the negotiated studies have already been submitted, along with copies of the (robust) study

[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]

summaries, can be found in Annexes II and III, respectively.

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.

If you have any questions regarding the suspension of the assessment of your submission and the next steps, please contact the ECHA Helpdesk under https://echa.europa.eu/fi/contact/reach and refer to this decision.

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.

[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 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. In addition, Article 30(2) of the REACH Regulation establishes that, if a relevant study is not available within the SIEF, and no agreement is reached as to who should conduct it, ECHA shall specify which registrant shall perform the test.

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 implementing a clear and comprehensible cost itemisation and justification as set out in Article 2 of the Implementing Regulation 2016/9. A potential registrant has the right to receive, without undue delay, said itemisation that links cost items with data requirements and provides a justification for each cost item. The information provided must be detailed enough to allow the potential registrant to assess the specific need of the studies, their individual costs and the relevance of administrative costs. This information is essential to enable a potential registrant to assess whether the requested compensation for access to data and to the joint submission is fair, transparent and non-discriminatory as required by REACH and the Implementing Regulation 2016/9.

[redacted]

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 31 May 2018 and by the Other Party on 8 June 2018.

6. On 19 June 2017, the Claimant asked which company the Other Party represented and informed them of a third party that had offered to act as Lead Registrant. Further, the Claimant asked what would be an estimated cost for [redacted] registration.

7. On 27 June 2017, the Claimant sent a reminder of the previous message to the Other Party.

8. On 28 June 2017, the Other Party wrote that the third party mentioned by the Claimant did not intend to register anymore, and that the Letter of Access ('LoA') cost was not available yet because the studies had not been finished. On the same day, the Claimant asked whether the Other Party was planning to use read-across data and when the estimated costs would be available. On the same day, the Other Party replied that they were conducting [redacted] experiments on which the read-across decision would be based and could not estimate the dossier cost yet.

9. On 29 August 2017, the Claimant asked whether the Other Party's data-gap analysis and SIP had been completed and whether the cost of the registration was available already, because they needed this information in order to decide '*whether or not to do a registration*'.

10. On 1 September 2017, the Other Party replied that the registration would be '*finalized in the end of this year*' and that they would communicate the LoA cost once they knew it.

11. On 4 September 2017, the Claimant referenced the REACH Regulation and wrote that many decisions on cost sharing and data should be taken within the SIEF. They asked what the overall cost in the tonnage band [redacted] would be and how the costs were shared.

12. On 5 September 2017, the Other Party wrote that they would register in the tonnage band [redacted] and that the estimated LoA cost for [redacted] would be '*around EUR* [and the Other Party would] *share the cost according to the actual registration numbers.*' They also attached the SIP in the message.

13. On 3 October 2017, the Claimant requested a phone call with the Other Party in order to discuss the SIP.

14. On 9 October 2017, the Other Party sent a message with the SIP attached.

15. On 26 October 2017, the Claimant wrote that they had not received a reply to their email dated 3 October 2018. They also noted that the Other Party had not asked '*all SIEF members to confirm* [the Other Party] [redacted] *as Lead registrant, neither* [had the Other Party] *asked if any SIEF member* [had] *studies.*' Further, the Claimant asked if the Other Party had requested data from a consortium that had registered similar substances. Still on the same day, the Claimant asked the Other Party to inform if they still planned to register the Substance.

16. On 31 October 2017, the Other Party asked the Claimant to provide '*study results of* [redacted] and informed that the SIP was still to be confirmed following '*the analysis test*'.

17. On 18 December 2017, the Claimant requested the Other Party to send an updated SIP and asked whether the lead dossier had been submitted, whether a LoA could be bought, and whether a cost itemisation was available.

18. On 19 December 2017, the Other Party wrote to the other pre-registrants informing of their role as the Lead Registrant for the Substance and asking if the co-registrants would have any data available for the purposes of the registration. In addition, they indicated that the tonnage band would be [redacted], with Annex [redacted] submission before an update to Annex [redacted] Finally, they wrote that the LoA was not yet available because of unfinished tests. On the same day, the Claimant replied that they had no data to provide, repeated their request for an update on the SIP and asked for the timeline for the submission of the lead dossier. In addition, they requested to receive before the end of the year the SIEF agreement, LoA cost information and a cost itemisation of the used studies and other costs.

19. On 20 December 2017, the Other Party replied that the SIP covered [redacted] and suggested that if the Claimant worried that their product would not match the SIP, the Claimant should conduct their own test, and inform the Other Party of the results. The Other Party also estimated that the LoA price would be '*around* [redacted] *EUR*' and that the Annex [redacted] dossier would be submitted '*in the first quarter 2018.*'

20. On 21 December 2017, the Claimant asked whether their substance was within the SIP proposed by the Other Party.

21. On 28 February 2018, the Claimant repeated their question related to the SIP. Further, they asked the Other Party to confirm before 5 March 2018 that the dossier would be submitted before the end of March. On the same day, the Other Party confirmed that the Claimant's substance could be '*contained*' in the SIP, and that the dossier would be submitted before the end of March if the laboratories had finished the studies by then. After finalising the dossier, the Other Party would '*contact with ECHA to submit the dossier according to DCG* [Directors' Contact Group] *advises*' and '*inform* [the Claimant immediately].'

22. On 23 March 2018, the Other Party informed the Claimant that they would submit the dossier '*in coming days*' and that the LoA cost for the tonnage band [redacted] was [redacted] *EUR and* [they would] *recalculate the price in this end of year*' to take into account possible reimbursements.

23. On 27 March 2018, the Claimant requested the following information from the Other Party: the number of registrants in each tonnage band, the principles of cost sharing, which studies were used and their costs, as well as the costs for dossier preparation, administration and other cost items. They also requested the SIEF agreement from the Other Party.

24. On 4 April 2018, the Claimant requested instructions from the Other Party on how to join the joint registration, as ECHA had '*apparently*' approved the late submission of the lead dossier and indicated that the Other Party would '*also receive instructions for the submitting of the member dossiers.*'

25. On 9 April 2018, the Other Party replied that they had not received such instructions but ECHA had confirmed that they '*could submit the dossier according* [to] *DCG 10.3.*'

26. On 10 April 2018, the Other Party asked the Claimant to fill in and return a Joint Submission Form by 20 April 2018, after which they would '*receive a down payment invoice* [redacted] *to confirm* [the] *participation of all new joint registrants and* [...] *a SIEF agreement for* [their] *sign off*'. After paying the down payment invoice and signing the SIEF agreement, the Claimant would be '*provided with a final cost overview and settlement invoice. Upon payment of the settlement invoice* [they would] *be granted access to the Joint Submission*' and the required documents and files. On the same day, the Claimant asked the Other Party to adapt the SIP and send a draft SIEF agreement '*to understand how future cost would be shared.*' The Claimant requested that all registrants should contribute to the dossier costs, including affiliates.

27. On 11 April 2018, the Other Party sent the SIEF agreement and informed of a SIP update. On the same day, the Claimant acknowledged the SIP update and disagreed with the SIEF agreement's clauses stating that affiliates would '*only pay once for the LoA.*' They asked the Other Party to change the SIEF agreement so that each affiliate would share the costs, citing an ECHA helpdesk answer in the message.

28. On 12 April 2018, the Other Party replied that many other companies had a similar clause in their SIEF agreements. Therefore, they would keep it until two or more affiliates of a same company would like to register and then the matter could be discussed among all SIEF members. On the same day, the Claimant informed that they did not agree with the terms of the SIEF agreement because of the affiliate clause and would not therefore sign it before it was changed. They did not consider it fair that '*one company* [paid] *once for a LoA, but* [would be] *able to do 10 registrations.*'

29. On 16 April 2018, the Other Party replied that they would not change the affiliate clause because it '[was] *not mandatory*' and '*the time* [was] *very tight*', but once such a case was encountered, it could be discussed among the SIEF members. The Other Party attached two SIEF agreements for different substances in the message '*for reference only,*' reminding the Claimant that they have registered other substances previously with similar SIEF agreements.

30. On 17 April 2018, the Claimant replied that in previous registrations the number of registrants had been higher, whereas in this case '*there* [were] *very few registrants and this* [would] *have a big influence on the cost*.' They suggested an amendment to the SIEF agreement, stating that '*all affiliates should contribute to the cost*.'

31. On 31 May 2018, the Claimant informed the Other Party that, according to ECHA, the Claimant's dossier would have to be submitted on the same day. The Claimant indicated that they had tried to reach the Other Party by phone and asked them to return the call. On the same day, the Claimant informed the Other Party that ECHA had '*advised* [them] *to do a data sharing dispute, considering the lack of communication* […] *and the fact that* [they did] *not have a token*', meaning that the Claimant could not '*make use of the provision of the DCG.*' The Claimant indicated that they would '*terminate the dispute*' in case they received a token and were able to submit their dossier during the same day.

32. On 31 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

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

34. ECHA notes that after initial discussions, the negotiations between the parties reached a standstill when they disagreed on the SIEF agreement, namely on the cost-sharing principle for affiliates joining the joint registration. The Claimant considered said clause unfair, and explained their views to the Other Party. In particular, they considered that due to this clause each time a company would allow an affiliate to register, this affiliate would not have to compensate the co-registrants for the registration. The Other Party did not address the Claimant's arguments and replied instead that they would not change this clause in the SIEF agreement because they did not consider it mandatory to do so and there was not enough time remaining before the REACH registration deadline.[5] By refusing to discuss the Claimant's reasons for disagreeing with the affiliate clause in the SIEF agreement, the Other Party did

[5] The Other Party, 16 April 2018.

[redacted]

not make every effort to find an agreement and prevented the Claimant from joining the joint submission.

35. Further, the Claimant had requested the SIEF agreement already in December 2017[6] and information related to the cost-sharing model in September 2017.[7] The Other Party only provided a draft SIEF agreement in April 2018 after the Claimant's repeated reminders and requests. Pursuant to Article 2 of Implementing Regulation 2016/9, an existing registrant shall provide a data sharing agreement with an itemisation without undue delay. According to Article 30(1) of the REACH Regulation, the existing registrant shall react within a month. The delay in the Other Party's reaction is thus a failure to make every effort in itself.

36. In addition, the Other Party's late reaction left the Claimant, who had to register by end of May, with very little time to negotiate. When it refused to discuss the affiliate clause due to time pressure, the Other Party further made the Claimant suffer from the delay which was attributable to the Other Party. In any event, the Other Party had to make every effort to find a fair, transparent and non-discriminatory agreement and could not refuse to discuss the fairness of the agreement. This applies all the more, where the Other Party provided the SIEF agreement with a delay of several months. Therefore, the Other Party did not make every effort in the negotiations.

D. Conclusion

37. Considering their efforts to receive the SIEF agreement and negotiate its content, and considering the filing of the dispute as the last resort in the negotiations, the Claimant made every effort to reach an agreement, whereas the Other Party failed to do so.

38. Consequently, ECHA can give permission to refer to existing vertebrate studies, if they have been submitted, in accordance with Article 30(3) of the REACH Regulation.

39. However, not all studies subject to the negotiations have been submitted yet. The Other Party has applied for DCG solution issue 10.3,[8] explaining that some studies do not exist yet and that the performance of the studies is delayed. The Other Party has demonstrated to ECHA that the relevant studies are being conducted. ECHA has thus requested the Other Party to submit the complete information by [redacted].

40. Therefore, ECHA will grant a permission to refer to the studies once they have been submitted to ECHA.

41. In case studies subject to the negotiations will not be submitted by [redacted], ECHA may, depending on whether the studies exist, take a decision allowing the Claimant to carry out the studies in accordance with Article 30(2) of the REACH Regulation or to proceed with registration in accordance with Article 30(3) of the REACH Regulation.

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[6] The Claimant, 19 December 2017.

[7] The Claimant, 4 September 2017.

[8] ECHA Director's Contact Group issue 10.3 "Completeness of registration dossiers – Data required in Annexes VII and VIII of REACH not yet available by the registration deadline" (https://echa.europa.eu/fi/about-us/partners-and-networks/directors-contact-group/dcg-issues).

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