[redacted]

Helsinki, 29 June 2018

The Claimant

[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 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 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 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 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 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[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 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. Further, Article 3(1) of the Commission Implementing Regulation 2016/9 requires ECHA to ensure that all registrants of the same substance are part of the same registration for the substance. Article 3(3) of the Implementing Regulation 2016/9 also confirms that a potential registrant may decide to invoke Articles 11(3) or 19(2) of REACH in order to submit separately all or part of the relevant information in Article 10(a) of REACH. In such cases, Article 3(3) of the Implementing Regulation 2016/9 requires ECHA, upon the potential registrant's request, to ensure that this separate submission of information remains part of the existing registration for the substance.

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 must provide an itemisation of costs without undue delay, as laid down in Article 2(2) of the Implementing Regulation 2016/9. This itemisation 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 on 27 March 2018 and by the Other Party on 27 April 2018.

6. On 17 October 2016, the Claimant contacted the Other Party and expressed their interest in joining the registration for the substance. They asked for '*the SIP* [i.e. Substance Identity Profile] *file, as well as the SIEF* [i.e. Substance Information Exchange Forum] *Agreement and the current price for a Letter-of-Access for a full substance registration*'.[5] The Claimant sent

[5] Claimant; 17 October 2016.

[redacted]

a reminder with such requests on 8 February 2017.[6] On 14 February 2017 the representative of the Other Party's consortium responded by sending the SIP and an earlier SIEF communication with details of the Letter of Access to the Claimant. The representative further informed the Claimant that they had proposed to the Lead Registrant and the consortium members '*to evaluate, and if necessary, to update the existing SIEF Agreement and the cost structure for the LoAs* [i.e. Letters of Access].'[7]

7. On 13 March 2017, the Claimant enquired about the status of the SIEF Agreement update, the cost structure of the Letter of Access and the degree of purity mentioned in the SIP, i.e. '[redacted]% [sic]'.[8] On 20 March 2017, the Other Party replied that it would take at least 6 to 8 weeks for the SIEF Agreement to be updated, but the Claimant '*may work with the official existing figures and in case of balance in your favour resulting from the cost review we will arrange a credit in your favour later this year.*' The Other Party added that the [redacted]% figure had been fixed by the companies of the consortium due to [redacted].[9]

8. On 3 April 2017, the Claimant requested a cost breakdown for the tonnage band [redacted].[10] On 10 April 2017, the Other Party replied that they would convey the Claimant's query to the members of the consortium.[11]

9. On 9 June 2017, the Claimant further asked for news concerning the cost breakdown as well as the status of the SIEF Agreement update. They also enquired whether it would be possible to widen the boundary composition of the substance.[12] On 30 June 2017, the Other Party replied that there were no news concerning the updated SIEF Agreement and the cost breakdown. The Other Party also noted that it would be for the members of the consortium to decide on the question of whether the boundary composition could be widened.[13]

10. On 10 July 2017, the Claimant enquired when the SIEF Agreement and the cost breakdown would be available and when the consortium would decide on the widening of the boundary composition.[14] On 28 July 2017, the Claimant again asked when the new SIEF Agreement and the cost breakdown would be available.[15] On 1 August 2017, the Other Party replied that the consortium would look into the matter after the summer holidays.[16]

11. On 8 and 19 September 2017 the Claimant sent reminders to ask whether there were any news regarding the SIEF Agreement, the cost breakdown and the widening of the SIP.[17,18] On 19 September 2017, the Other Party responded that they were '*not confident if the* [consortium members] *will widen the SIP. Maybe* [the Claimant has] *to deal with this issue with ECHA when submitting* [their] *registration.*'[19] On 20 September, the Other Party added that they were going to '*evaluate the cooperation* [i.e. the consortium] *rule*' and hoped to be

---

[6] Claimant; 08 February 2017.
[7] Other Party; 14 February 2017.
[8] Claimant; 13 March 2017.
[9] Other Party; 20 March 2017.
[10] Claimant; 03 April 2017.
[11] Other Party; 10 April 2017.
[12] Claimant; 09 June 2017.
[13] Other Party; 30 June 2017.
[14] Claimant; 10 July 2017.
[15] Claimant; 28 July 2017.
[16] Other Party; 01 August 2017.
[17] Claimant; 08 September 2017.
[18] Claimant; 19 September 2017.
[19] Other Party; 19 September 2017.

[redacted]

able to get back to the Claimant with '*good news*' soon.[20]

12. On 20 September[21], 24 October[22] and 1 November 2017, the Claimant again enquired about the SIEF Agreement and the cost breakdown and sent reminders.[23] In their email of 24 October, the Claimant also asked why it might prove difficult to widen the SIP. On 9 November 2017, the Claimant asked the Other Party's representative to remind the Other Party to reply to the Claimant's emails and phone calls.[24] On 21 November, the Other Party informed the Claimant that the latter's '*application for access*' would be examined by the steering committee of the consortium on 4 December 2017.[25]

13. On 8 December 2017, the Claimant observed that the SIEF Agreement was not yet available for review though '*it's been almost a year since* [the Claimant] *first asked for the document.*' The Claimant also reiterated that they did not understand why the SIP could not be widened.[26] On 14 December 2017, the Claimant notified the Other Party that, unless the SIEF Agreement and the cost breakdown are provided or a schedule for the preparation of these items is fixed, the Claimant '*will be forced to contact ECHA.*' The Other Party was given two days to provide a response.[27]

14. On 18 December 2017, the Other Party sent a letter to the Claimant with information on the outcome of the steering committee held on 4 December. The letter required the Claimant to supply a '*statement about the nature of the substance to be registered*' and a '*product data sheet (technical file) and flowsheet of the production process*'. Only upon a positive evaluation of these documents would the steering committee grant the Letter of Access to the Claimant.[28]

15. In two emails sent to the Other Party on 15 January 2018, the Claimant informed the Other Party that they would not need a final SIEF Agreement immediately. For the moment, a template would suffice.[29] On the same day, the Other Party reminded the Claimant of the need to provide the documents requested by the steering committee. Upon submission of these documents by the Claimant, the Other Party would be able '*to explain to* [the Claimant] *all future steps to receive the SIEF Agreement.*' The argument behind the request was that '*as Lead Company* [the Other Party] *need to protect the position of* [their] *SIEF and be sure that* [their] [redacted] *included in Joint Submission is suitable for* [the Claimant's] *customers.*'[30]

16. On 16 January 2018, the Other Party sent to the Claimant a SIEF Agreement template featuring the unchanged boundary composition.[31] On 26 February 2018, the Claimant again asked for an updated SIEF Agreement.[32]

17. On 28 February 2018, the Other Party reminded the Claimant to send the requested documents.[33] On 1 March 2018, the Claimant replied by sending a link to their company's website on which the Other Party could find '*several specification sheets, product data sheets,*

---

[20] Other Party; 20 September 2017.
[21] Claimant; 20 September 2017.
[22] Claimant; 24 October 2017.
[23] Claimant; 01 November 2017.
[24] Claimant; 09 November 2017.
[25] Other Party; 21 November 2017.
[26] Claimant; 08 December 2017.
[27] Claimant; 14 December 2017.
[28] Other Party; 18 December 2017.
[29] Claimant; 15 January 2018.
[30] Other Party; 15 January 2017.
[31] Other Party; 16 January 2018.
[32] Claimant; 26 February 2018.
[33] Other Party; 28 February 2018.

SDS and technical information about [their] *products*.' The Claimant again requested the SIEF Agreement '*to sign*.'[34] On the following day, the Other Party noted that they had not been able to find relevant information on the Claimant's website, and that what they especially wished to know was whether the Claimant's substance was [redacted] or [redacted] The Other Party argued that '*this is the most important item for us because our SIP and consequently* [redacted] *study* [redacted] *were formulated for* [redacted]'.[35,36] On the same day, the Claimant pointed out that [redacted].[37]

18. On 12 March 2018, the Claimant reminded the Other Party to send the SIEF Agreement.[38] The Other Party responded to the Claimant as follows: '*it is true that* [redacted] *but* [they] *have to give all the information as per provision of art. 10 and 12 lett. a) and b) of the Regulation*.'[39] The Claimant argued that information about the manufacturing process and the nature of the substance are confidential and they '*are not obliged to share such information for REACH purposes*.' The Claimant raised the objection that even if they had to opt out from some endpoints, the obligation to register jointly would remain in place. The Claimant requested the Other Party to send them the SIEF Agreement by 27 March or they would file a dispute with ECHA.[40]

19. On 27 March 2018, the Other Party sent an email to the Claimant arguing that co-registrants have an obligation to agree with each other on the sameness of the substance.[41] On the same day, the Claimant noted that '*the sameness of* [their] *substance needs to be proven to ECHA and not to the lead registrant and of course we are willing to prove this in our registration dossier. Information about the manufacturing process or the nature of the substance is confidential business information and* [they] *do not need to exchange this information with the lead registrant for a REACH registration of a* [redacted] *substance of* [redacted] *purity.*' The Claimant further noted that they had not yet received the requested SIEF Agreement, hence they would initiate a dispute.[42]

20. On the same day, 27 March 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

21. As explained in section A. of Annex I above, ECHA assesses the efforts made by the parties in the negotiations. These efforts were outlined in section B.

22. In order to make every effort to reach an agreement, Article 2(2) of the Implementing Regulation 2016/9 requires that upon request, the existing registrant shall provide the itemisation of costs to the potential registrant without undue delay. By virtue of Articles 2(1)(a) and 2(1)(b) of the same regulation, the itemisation needs to list all costs related to data as well as to administrative costs. The itemisation needs to include proof and justification for all cost items. Such information serves as a basis and starting point for the cost sharing discussions between the parties, as it enables a potential registrant to understand and assess

---

[34] Claimant; 01 March 2018.
[35] Other Party; 02 March 2018.
[36] The text [redacted]' is bold and underlined in the original correspondence.
[37] Claimant; 02 March 2018.
[38] Claimant; 12 March 2018.
[39] Other Party; 12 March 2018.
[40] Claimant; 20 March 2018.
[41] Other Party; 27 March 2018.
[42] Claimant; 27 March 2018.

[redacted]

the requested costs on an objective basis.

23. Moreover, making every effort means that an existing registrant also needs to address other requests by a potential registrant, e.g. concerning the form or, where foreseen, the contractual basis for their cooperation. ECHA notes that in practice such agreements are frequently referred to as SIEF agreements. In addition, the 'one substance, one registration' principle provided in Article 3 of the Implementing Regulation 2016/9 entails that, in case newcomers who have to register the same substance within the existing joint submission are not covered by the previously agreed SIP, the SIP must be adapted so that the newcomers are not excluded from the joint submission.

24. ECHA notes that the Claimant asked for information regarding the SIP and the SIEF agreement in their first email of 17 October 2016, and a cost itemisation with their requests on 13 March and 3 April 2017. These emails were followed by repeated and consistent reminders, and by the request of the Claimant to widen the SIP to cover their composition, which were not answered by the Other Party with reference to the need to consult the consortium members. This led up to a meeting of the consortium on 4 December 2017 to discuss the Claimant's requests. After the meeting of the consortium members on 4 December 2017, however, rather than providing the requested SIEF agreement and the cost itemisation to the Claimant, the Other Party requested additional information on the Claimant's substance and production process, and stated that otherwise they would not provide the requested information.

25. ECHA notes that the Claimant made consistent efforts when requesting the cost breakdown, as it reminded the Other Party about this request, and accepted the explanations for the initial delays incurred by the Other Party. At a later stage, when faced with new preconditions set by the consortium to receive the cost itemisation and SIEF agreement, the Claimant (i) argued that the requested information was not needed for the Other Party to provide that information and (ii) justified their refusal to share e.g. details of their production process with reference to confidential business information. The Claimant made effort by explaining to the Other Party that the substance identity needs to be proven to ECHA and not to the Lead Registrant. The Claimant further tried to seek a constructive way forward by restraining themselves to requesting preliminary documents instead of final documents while the discussion on the substance sameness could be held in parallel. Thereby, the Claimant made efforts to advance the negotiations.

26. In turn, ECHA notes that during the entirety of the negotiations, i.e. for more than one year, the Other Party never provided a cost itemisation, despite the Claimant's requests and in disregard of the Other Party's obligation under the Implementing Regulation 2016/9 to provide an itemisation without undue delay upon request. As a result, the Other Party did not make every effort to reach an agreement. Similarly, they never provided the SIEF agreement despite the consistent requests from the Claimant. Further, by requiring the Claimant to disclose details about their substance while refusing to provide cost information, the Other Party arbitrarily set a precondition for updating the SIEF Agreement and for proceeding with the joint submission instead of making efforts to reach an agreement with the Claimant.

27. From the beginning of the negotiations until 8 December 2017, the Other Party frequently failed to address the requests from the Claimant and therefore to make every effort to enable meaningful data-sharing discussions. The Claimant instead made every effort to reach an agreement throughout the negotiations as they actively sought answers from the Other Party and sent several reminders to speed up the process. As the Claimant never received a cost breakdown or a data-sharing agreement (or SIEF agreement) for review, they could not have negotiated further and made any more efforts. Due to the Other Party's insistence on the issue of substance sameness, negotiations were at a standstill when the dispute application was filed.

D. Conclusion

[redacted]

28. The Claimant made every effort to reach an agreement, while the Other Party failed to make such effort.

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

E. Observations

30. It is important to note that on 8 January 2018 ECHA informed all registrants of the substance that '*the joint submission obligation has been breached, because separate joint submissions have been submitted for the same substance. All registrants are thus required to submit the requested information on the substance in a single joint submission by 1 August 2018.*' Thus, the Other Party had been notified of the need to secure a single joint submission for this substance and to make every effort to reach an agreement with potential registrants.

31. If the Other Party still had genuine concerns regarding substance identity, they could choose to initiate a separate submission under a different EC identifier. In such case the burden of proof would be on the Other Party to demonstrate that their separate submission does not breach the 'one substance, one registration' principle provided in Article 3 of the Implementing Regulation 2016/9.

32. Finally, ECHA highlights that the substance to be registered is [redacted] substance with [redacted] purity level. As noted by the Guidance for Identification (Appendix III, p. 118) 'the definition of the SIP should not take an overly conservative approach' resulting in the exclusion of potential registrants from the joint submission. In addition, substance identity may be verified at the stages of technical completeness check and compliance check or during the potential substance evaluation.