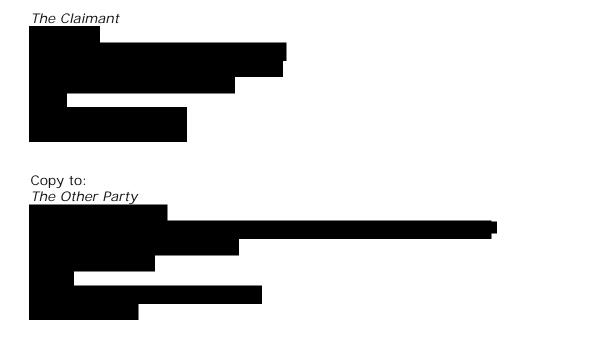




Helsinki, 21 November 2018



Decision number:
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 does not grant you the permission to refer to the information you requested from the Existing Registrant of the Substance, nor access to the joint submission.

This decision is adopted under Articles 30(3) and 11 of Regulation (EC) No 1907/2006 ('REACH Regulation')<sup>2</sup> 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')<sup>3</sup>.

The reasons for this decision are set out in Annex I.

<sup>1</sup> Acting as a third party representative pursuant to Article 4 of Regulation (EC) No 1907/2006. ECHA notes that where a lead registrant has made use of a third party representative according to Article 4 of the Regulation, the rights and obligations under REACH solely apply to the lead registrant.

 $<sup>^2</sup>$  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,  $O\!J$ L 396, 30.12.2006, p.1, as last amended.

<sup>&</sup>lt;sup>3</sup> 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.





This decision will be published in an anonymised version on ECHA's website<sup>4</sup>.

### B. Recommendation

Under Articles 30 and 11 of the REACH Regulation and the Commission Implementing Regulation, the parties must make every effort to reach an agreement on the sharing of the information and costs related to the access to the joint submission. Therefore, the parties should continue to negotiate in order to reach an agreement that will be satisfactory for both parties. If the future negotiations fail, the Claimant will be free to submit another claim, covering the efforts that have occurred after the submission date of the dispute claim, that is, after 31 May 2018.

Advice and further observations are provided in Annex II.

## 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 <a href="http://echa.europa.eu/web/guest/regulations/appeals">http://echa.europa.eu/web/guest/regulations/appeals</a>.

Yours sincerely,

Christel Schilliger-Musset<sup>5</sup>

Director of Registration

-

<sup>&</sup>lt;sup>4</sup> Available at <a href="https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach">https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach</a>.

<sup>&</sup>lt;sup>5</sup> 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.





# 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.

# B. Summary of facts

- 4. This summary of facts is based on the documentary evidence submitted by the Claimant on 31 May 2018 and by the Other Party on 20 June 2018.
- 5. On 12 February 2018, the Other Party reminded the SIEF members, with intention to register before June 1st, about their letter of access (LoA) and token procedure. They highlighted that those potential registrants should proceed requesting the LoA 'now', explaining that 'the LoA procedure takes at least a couple of weeks before [the potential registrant] obtain[s] the token and can proceed with the submission of the coregistration dossier'. In addition, the Other Party warned the SIEF members that 'co-registration may not be completed in time, if [their] request for the LoA is received after April 1st, 2018'.6
- 6. On 9 March 2018, the Claimant requested the Other Party to provide them with the LoA price for their tonnage band and the Substance Identity Profile (SIP). The Other Party followed both requests and on 13 March 2018 sent the Claimant the LoA application form to fill in. 8

<sup>8</sup> Other Party: 13 March 2018.

<sup>&</sup>lt;sup>6</sup> Other Party; 12 February 2018.

<sup>&</sup>lt;sup>7</sup> Claimant; 9 March 2018.



- 7. On 22 May 2018, the Claimant returned the filled LoA application form to the Other Party and requested the SIEF agreement, which was provided by the Other Party the following day.<sup>9</sup>
- 8. On 25 May 2018, the Claimant returned the signed SIEF agreement (hereinafter 'agreement'), which provides on page that The Claimant also stated

that they were awaiting the LoA invoice 'as soon as possible'.10

- 9. On 28 May 2018, the Claimant reminded the Other Party to provide the LoA invoice. In the same message the Claimant also requested the Other Party to confirm whether the proof of payment was 'enough to receive the information to make the registration', given that there were 'only four days for deadline'.<sup>11</sup> In the same message, the Claimant requested that, in case the proof of payment had not sufficed for registration, the Other Party should have provided instructions for speeding up the process<sup>12</sup>. On this day, 28 May 2018, the Claimant sent an additional reminder regarding the LoA invoice<sup>13</sup>, and the Other Party provided the invoice on the same day<sup>14</sup>.
- 10. On the following day, 29 May 2018, the Other Party communicated that they had received the proof of payment and requested one of their employees to provide the Claimant with the token, name of the joint submission and the countersigned agreement.<sup>15</sup>
- 11. On 30 May 2018, the Claimant sent three reminders to the Other Party requesting the token and the joint submission name. 16
- 12. On 31 May 2018<sup>17</sup>, the Claimant requested again the Other Party to provide the token and name of the joint submission<sup>18</sup>. The Other Party replied that they had contacted the lead registrant (LR)<sup>19</sup> of the substance and were waiting '[the lead registrant's] signature of the SIEF agreement/LoA in order to send [to the Claimant] the token and the Joint Submission name'.<sup>20</sup> Shortly after, the Claimant sent another reminder, pointing out that they needed to submit the dossier 'in the next hour' and could not wait 'further delay'.<sup>21</sup> This was followed by a reply by the Other Party, informing the Claimant that they expected the LR to reply before '3pm'.<sup>22</sup>
- 13. In a follow up message, the Claimant stated that they 'need' the token 'before to 13 pm' as they had already signed the agreement and paid the LoA invoice 'two days ago'; 'independently [the Other Party] can sign the LoA before 13 pm'. 23 In the same message, the Claimant added that the Other Party could make an 'exception' given the urgency of their situation. The Other Party expressed their disappointment towards the Claimant's situation

<sup>&</sup>lt;sup>9</sup> Claimant; 22 May 2018.

<sup>&</sup>lt;sup>10</sup> Claimant; 25 May 2018.

<sup>&</sup>lt;sup>11</sup> Text highlighted in the original.

<sup>&</sup>lt;sup>12</sup> Claimant; 28 May 2018 at 9:26.

<sup>&</sup>lt;sup>13</sup> Claimant; 28 May 2018 at 15:00.

<sup>&</sup>lt;sup>14</sup> Other Party; 28 May 2018.

<sup>&</sup>lt;sup>15</sup> Other Party; 29 May 2018

<sup>&</sup>lt;sup>16</sup> Claimant; 30 May 2018 at 9:42, 10:07 and 14:47

 $<sup>^{\</sup>rm 17}$  On 31 May 2018, 19 messages were exchanged between the parties.

<sup>&</sup>lt;sup>18</sup> Claimant; 31 May 2018 at 9:25.

<sup>&</sup>lt;sup>19</sup> Note that here 'the Other Party' is a third party representative (TPR) of the lead registrant of the substance.

<sup>&</sup>lt;sup>20</sup> Other Party; 31 May 2018 at 9:58.

<sup>&</sup>lt;sup>21</sup> Claimant; 31 May 2018 at 10:19.

<sup>&</sup>lt;sup>22</sup> Other Party; 31 May 2018 at 11:46.

<sup>&</sup>lt;sup>23</sup> Claimant; 31 May 2018 at 12:00.



and informed that the provision of the token was the responsibility of the LR adding that they are 'continuing to push the pressure on [the LR]'.<sup>24</sup>

- 14. The Claimant replied that they were surprised to hear that the Other Party was not the LR and requested the Other Party to provide the name of the LR.<sup>25</sup> In the same message, the Claimant requested the Other Party to explain why they had not received the token yet, given that they had already signed the agreement and paid the LoA invoice. Further, the Claimant repeated their request that the Other Party should make an exception given the situation and provide the token before the LR had signed the agreement. In their reply, the Other Party explained that they were acting as a third party representative (TPR), adding that they had contacted the LR, insisting on the urgency of Claimant's situation, and were awaiting their reply.<sup>26</sup>
- 15. In their reply, the Claimant asked the Other Party to inform whether they had heard back from the LR and informed they had been advised by ECHA to proceed with litigation 'as soon as possible'.<sup>27</sup> The Other Party informed the Claimant that they were currently on the phone with the LR and requested the Claimant to 'hold on' before launching the dispute.<sup>28</sup> The Claimant inquired again whether there was any news<sup>29</sup> to which the Other Party replied that 'unfortunately' they did not have any information but they 'expected' it soon.<sup>30</sup> Upon which the Claimant informed of their intent to launch the dispute.<sup>31</sup>
- 16. On 31 May 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

- 17. As explained in section A., ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B. Making every effort means that the negotiating parties raise their concerns timely and give each other reasonable time to reply to questions or accommodate requests.
- 18. On 12 February 2018, the Other Party had sent a reminder to all SIEF members with an obligation to register by 31 May 2018<sup>32</sup>, which was a clear communication from the Other Party urging potential registrants to take action on the LoA procedure in case they intend to register on time, approximately three months before the registration deadline.
- 19. The Claimant had the intention to register their substance by the deadline of 31 May 2018. After having requested the LoA price (one month following the Other Party's reminder) and swiftly receiving the LoA application form by the Other Party, the Claimant remained silent and did not contact the Other Party for a period of over two months. This lack of action from the Claimant shows that they did not make efforts to engage timely in the negotiations before the registration deadline became immediate.

 $<sup>^{24}</sup>$  Other Party; 31 May 2018 at 12:14.

<sup>&</sup>lt;sup>25</sup> Claimant; 31 May 2018 at 12:24.

<sup>&</sup>lt;sup>26</sup> Other Party; 31 May 2018 at 14:17.

<sup>&</sup>lt;sup>27</sup> Claimant; 31 May 2018 at 14:56.

<sup>&</sup>lt;sup>28</sup> Other Party; 31 May 2018 at 15:00.

<sup>&</sup>lt;sup>29</sup> Claimant; 31 May 2018 at 16:04.

<sup>&</sup>lt;sup>30</sup> Other Party; 31 May 2018 at 16:11.

<sup>&</sup>lt;sup>31</sup> Claimant; 31 May 2018 at 16:12.

<sup>32</sup> Claimant; 12 February 2018.



- 20. On 22 May 2018, the Claimant came back to the Other Party with the filled LoA application form and requested the SIEF agreement.<sup>33</sup> On 25 May 2018, the Claimant provided a signed copy of the Other Party's SIEF Agreement to the Other Party. On 29 May 2018, two days before the registration deadline, the Claimant provided the proof of payment for the LoA. On the same day, the Other Party confirmed the receipt and immediately instructed one of their staff to provide the token to the Claimant. ECHA recognises that the Claimant made every effort towards the very end of the negotiations when the Claimant signed the SIEF Agreement and obtained the confirmation from the Other Party that the payment was received by the Other Party and the token would now be sent.
- 21. Immediately after this payment and up to the deadline, the Claimant sent numerous reminders<sup>34</sup> to the Other Party stressing the urgency of their situation and requesting the Other Party to provide the token 'as soon as possible <sup>35</sup>. However, the SIEF agreement provided to ECHA as part of the evidence and signed by the Claimant provides that aving signed, and not contesting the terms of this agreement, the Claimant acknowledged that the Other Party may not be able to provide the token by the deadline if the payment of the invoice is made later than days before the deadline. As a result, it seems that the Claimant submitted the dispute claim hastily and without giving themselves and the Other Party a chance to examine all relevant issues more thoroughly.
- 22. ECHA observes that the Other Party could have made more efforts to reach an agreement. They let the Claimant believe that the token and the joint submission name would be provided upon payment of the invoice and failed to inform the Claimant that these items were not going to be provided in time for the deadline. In this respect, some communication issues emerged between the Lead Registrant and the TPR in the last stage of the negotiations. On 31 May 2018, the TPR informed the Claimant that the provision of the token was 'the responsibility of the Lead 36 and that they were waiting for the lead registrant to sign the SIEF agreement. The Claimant expressed their surprise and disappointment at the fact that the party they had been negotiating with did not seem to have a mandate to bring the negotiations to successful completion. ECHA notes that lead registrants and TPRs should act diligently throughout the negotiations and that every action of a third party representative is valid for and against the registrant. Still, the Other Party proved to be proactive in contacting potential registrants early on and, during the negotiations, in attempting to accommodate the Claimant's request by providing the LoA application form, the SIEF agreement, the SIP and the LoA invoice in a timely manner. Hence, the Other Party made some efforts in these negotiations.

### D. Conclusion

- 23. By not taking action timely and not giving reasonable time to the Other Party to accommodate their request, the Claimant did not make every effort to reach an agreement on access to the joint submission and the sharing of information. The fact that the Other Party also failed to make every effort does not change the position of the Claimant in this respect.
- 24. Therefore, ECHA does not grant the Claimant access to the joint submission.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

<sup>&</sup>lt;sup>33</sup> Claimant; 22 May 2018.

<sup>&</sup>lt;sup>34</sup> Claimant; 30 May 2018; Claimant; 31 May 2018 at: 9:25, 10:19, 12:00, 12:24, 13:30, 14:47, 14:56, 15:19,

 <sup>35</sup> Claimant; 31 May 2018 at 14:47.
 36 Other Party; 31 May 2018 at 12:14.





ECHA stresses that both parties still share the common data-sharing and joint submission obligation, and are therefore still required to make every effort to reach an agreement on the sharing of the information and of their related costs.

If future negotiations fail and the Claimant wishes to submit another dispute claim, ECHA's dispute assessment will cover the efforts made by the parties subsequently to the dispute claim that is the subject of the present decision. ECHA notes, in this respect, that the Claimant could not make any further efforts after having signed the SIEF agreement provided by the Other Party, making the payment and receiving confirmation that the payment was received.

The Agency also points out that a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would. Accordingly, ECHA strongly encourages the parties to continue their efforts to reach an amicable agreement that will be satisfactory for both parties having regard to the findings made by ECHA in the present decision.

Finally, with regard to the 31 May 2018 registration deadline, ECHA notes that the Claimant has received a token and instructions to make a temporary registration submission in light of the dispute assessment. Once the appeal period against the present decision has elapsed, ECHA will remove the temporary submission made by the Claimant in this context, unless the Claimant either (i) reaches an agreement with the existing registrant(s) and informs ECHA thereof; or (ii) submits a new dispute within this period.

<sup>&</sup>lt;sup>37</sup> Please note that this section does not contain elements that ECHA took into consideration in its assessment of the parties' efforts in their negotiations. ECHA's assessment of the dispute is set out only in the section 'C. Assessment' of Annex I. The Annex II 'Advice and Further Observations' aims only at providing further advice and information that can be helpful for the parties in the future of their discussions on data sharing and joint submission obligations.

"ECHA reminds you that following Article 16 of Regulation (EC) No 1049/2001, the documents attached are subject to copyright protection."  $\,$