

10 September 2019

The Claimant

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Copy to:

The Other Party

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

Sent via REACH-IT

Reference number: [REDACTED]

ECHA'S ASSESSMENT AND REQUEST FOR PROOF OF PAYMENT RELATING TO YOUR DISPUTE CLAIM

The European Chemicals Agency (ECHA) has examined the information you submitted on 26 July 2019 with reference number [REDACTED], regarding a failure to reach an agreement with [REDACTED] on sharing of data pursuant to Article 27(5) of Regulation (EC) No 1907/2006 ('REACH Regulation')¹, for the substance [REDACTED] (the 'Substance') with EC number [REDACTED].

ECHA has examined the efforts of the parties to reach an agreement on the sharing of the data and the costs in accordance with their obligation under Article 27 of the REACH Regulation, as reinforced by Articles 2 to 4 of the Commission Implementing Regulation (EU)

¹ Regulation (EC) No 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.

2016/9 on joint submission of data and data sharing in accordance with REACH ('Implementing Regulation 2016/9')². For this purpose, it assessed whether you have made every effort to find an agreement with the existing registrant.

On the basis of the documentation supplied, and pursuant to Article 5 of the Implementing Regulation 2016/9,

ECHA intends to grant you permission to refer to the information you requested from the Existing Registrant of the Substance.

The facts and the considerations forming the basis for this assessment can be found in the attached annex. A final decision will be issued upon receipt of the proof that you have paid the existing registrant a share of the costs incurred pursuant to Article 27(6) of the REACH Regulation.

The REACH Regulation only gives ECHA a competence to examine whether the conditions for granting permission to refer are met (*i.e.* whether the parties have made every effort to find an agreement and a proof of the payment is provided). However, REACH does not mandate ECHA to determine the appropriateness of the share of cost, which may eventually be subject to the assessment of a competent national court.

General observations

ECHA would like to remind you that the outcome of a dispute procedure can never satisfy any party in the way a voluntary agreement would. Therefore, ECHA strongly encourages the parties to negotiate further, taking into account the attached assessment, in order to reach an agreement that will be satisfactory for both parties. If a voluntary agreement is reached after the present notification, please inform ECHA accordingly.

Please note that this decision will be published in an anonymised version on ECHA's website³.

Contact

You can contact ECHA using the email address disputes@echa.europa.eu. Please state the above-mentioned reference number in any correspondence with ECHA in relation to this communication.

Yours sincerely,

William Broere⁴
Acting Head of Legal Affairs

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 communication has been approved according to the ECHA's internal decision-approval process.

Annex: ASSESSMENT**A. Applicable law**

1. When a dispute is submitted to ECHA pursuant to Article 27(5) of the REACH Regulation, ECHA performs an assessment of the efforts of the parties to reach an agreement (Article 5 of the Implementing Regulation 2016/9). According to Article 27(6) of the REACH Regulation and Article 3(2) of the Implementing Regulation 2016/9, ECHA may grant a permission to refer to the requested studies if the claimant has made every effort to find an agreement on the sharing of the data and the other party has failed to do so. The permission to refer is subject to the proof that the potential registrant has paid a share of the costs incurred by the previous registrant(s).
2. The obligation to make every effort to find an agreement that is fair, transparent and non-discriminatory is laid down in Articles 27(2) and 27(3) of the REACH Regulation. It is further defined in Articles 2 and 4 of the Implementing Regulation 2016/9.
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, making every effort means demonstrating cooperation and replying promptly and to all questions raised throughout the whole duration of the negotiations, as well as providing substantial elements in support of a concern raised by a party, which would potentially prevent the sharing of the data. When the parties face a dissent on an aspect, they need to clarify and explain their position, explore alternative routes and make suitable attempts in order 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

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 26 July 2019. The Other Party was invited to submit further documentary evidence of the negotiations by 16 August 2019, but it did not provide any.
6. On 20 December 2018, the Claimant contacted the Other Party, informing it of its intention to register the Substance and asking for the Substance Identity Profile ('SIP') and, if possible, the Chemical Safety Report ('CSR')⁵.
7. On the same day, the Other Party informed the Claimant that the latter would need to make an inquiry under Article 26 of the REACH Regulation. The Other Party also brought forward the fact that it [REDACTED]. It therefore offered to use the "affiliate approach", meaning that "both companies would be regarded together as one participant for future cost sharing models with potential further co-registrants"⁶.
8. On 9 April 2019, the Claimant replied that it had completed the inquiry and asked for the "sharing costs"⁷.
9. On 25 April and 7 May 2019, the Other Party informed the Claimant that it was undergoing insolvency proceedings. It explained that this would lead to some delay, as all details would need to be clarified with its insolvency administrator⁸. In addition, the Other Party informed that it "wishes to transfer" the lead registrant role to the Claimant.⁹
10. On 20 May 2019, the Claimant asked for additional information¹⁰, which was clarified by the Other Party the day after¹¹. A week later, the Claimant asked the Other Party to send the SIEF agreement¹².
11. On the same day, the Other Party informed the Claimant that the SIEF agreement could not be prepared before the beginning of July. The Other Party added that the agreement would require additional clauses reflecting the insolvency proceedings, but noted that it was probable that the parties "[would] be able to finish the procedure until the end of July"¹³.
12. Following these exchanges, the parties agreed on a way forward and on the schedule for the sending of the draft SIEF agreement and its signature, a meeting to review the documents on the proof of costs, and the transfer of the lead registrant role¹⁴.
13. After a reminder from the Claimant¹⁵, the Other Party informed the Claimant that "there [was] a problem", as "[its] liquidator [did] not want to sign or authorize a joint submission agreement"¹⁶. After first suggesting to provide the Claimant with the letter of access and

⁵ Email from the Claimant; 20 December 2018.

⁶ Email from the Other Party; 20 December 2019.

⁷ Email from the Claimant; 9 April 2019.

⁸ Email from the Other Party; 25 April 2019.

⁹ Email from the Other Party; 7 May 2019.

¹⁰ Email from the Claimant; 20 May 2019.

¹¹ Email from the Other Party; 21 May 2019.

¹² Email from the Claimant; 28 May 2019.

¹³ Email from the Other Party; 28 May 2019.

¹⁴ Email from the Claimant; 4 June 2019, and email from the Other Party; 21 June 2019.

¹⁵ Email from the Claimant; 15 July 2019.

¹⁶ Email from the Other Party; 17 July 2019.

token for free, as well as transferring “the Lead Status” and sending the IUCLID datafile¹⁷, the Other Party apologised and withdrew its suggestion, stating that “the liquidator has even prohibited to send a token”¹⁸. As a consequence, the Other Party suggested that the Claimant would “contact the ECHA”, as “there [was] nothing [it could] do at the moment”¹⁹.

14. On 26 July 2019, the Claimant submitted a claim under Article 27 of the REACH Regulation concerning the failure to reach an agreement on the sharing of data with the Other Party.

C. Assessment

15. Initially, the negotiations progressed well, as the Other Party promised to send a data sharing agreement to the Claimant and to transfer the lead registrant role to it. Both parties recognised that they were part of [REDACTED], and agreed that the Claimant would not need to pay compensation under the affiliate clause of the data sharing agreement. The Other Party informed the Claimant of the insolvency proceedings at an early stage of the negotiations, but did not consider these proceedings an obstacle to the negotiations. To the contrary, it agreed on a schedule for the sending of the draft SIEF agreement and its signature, a meeting to review the documents on the proof of costs, as well as the transfer of the lead registrant role in June.
16. Nevertheless, the Other Party later informed the Claimant that it could not agree on data sharing with the Claimant, and apologised for its change of mind. The Other Party wrote that the insolvency administrator was against signing or authorising an agreement, but gave no explanations for this refusal.
17. Making every effort to find an agreement means that the negotiating parties must justify their position and reply to the concerns raised by their negotiating partners. When a party raises a concern about the possibility of sharing the data with another party, it must explain its position and open a discussion on that point with the potential registrant. Thus, parties have to explain any legal constraints that they face so as to allow them to come up with solutions to ensure that their legal obligations are respected, including their obligation to share data.
18. The Other Party did not provide the Claimant with any further information concerning this situation, or explain the legal constraints that it may have faced in the insolvency proceedings. This was surprising, given that the Other Party initially did not consider the insolvency proceedings to be an obstacle to an agreement on data sharing. It made no further effort to clarify the reasons for this, or propose any other way forward. The Other Party did not send the Claimant for example the contact details of its insolvency administrator, which could have helped the parties to find an agreement. Ultimately, the Other Party suggested that the Claimant should contact ECHA, as if the Other Party had given up and considered the data sharing dispute the solution to the failure to find an agreement. This demonstrates a lack of effort in finding a negotiated agreement on data sharing from the Other Party.
19. The Claimant made every effort by replying promptly to the Other Party, clearly requesting the information it needed, bringing forward a proposal to the Other Party to send the SIEF agreement, as well as suggesting concrete ways to proceed. It was frustrated in its efforts by the Other Party’s refusal to conclude an agreement and its failure to explain whether and how sharing the data would conflict with the ongoing insolvency proceedings. Without such explanations, the Claimant could not develop alternative proposals on how to proceed.

¹⁷ Ibid.

¹⁸ Email from the Other Party; 17 July 2019.

¹⁹ Ibid.



D. Conclusion

20. In light of the above, ECHA considers that the Claimant made every effort to reach an agreement on the sharing of data, while the Other Party did not make every effort.

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