

[REDACTED]
Helsinki, 18 September 2018

The Claimant

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

Copy to:
The Other Party

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

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

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

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 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 website³.

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.

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>.

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-Musset⁴

Director of Registration

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.

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. 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. In case of companies with various affiliates that are separate legal entities, each legal entity shall fulfil its registration obligations separately and be part of the joint submission.⁵
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 also use clear explanations and terminology to enable the negotiations to progress in a timely manner. 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.

⁵ See the Guidance on data-sharing, Version 3.1., January 2017, p. 116

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 29 June 2018 and by the Other Party on 20 July 2018.
6. The discussion between the parties started on 25 May 2018. The Claimant asked if an affiliate company ('the Affiliate') of the non-EU manufacturer ('the non-EU manufacturer'), both of which the Claimant represented as only representative in accordance with Article 8 of the REACH Regulation, could use the Letter of Access ('LoA') without additional payment, following a provision in the Substance Information Exchange Forum ('SIEF') agreement that the Claimant had signed. The Claimant sent a reminder on 31 May 2018.
7. On 31 May 2018, the Other Party replied to the Claimant, indicating that the Other Party's regulatory department should answer the question and asking if the Claimant had any further questions. On the same day, the Claimant stated that they had already sent their question to the Other Party's regulatory department without receiving a reply. Further, the Claimant explained that they had purchased a LoA on behalf of the non-EU manufacturer and now the Affiliate would like to register as well for the tonnage band [REDACTED]. The Claimant asked again if '[the] Affiliate could use the [LoA] freely', adding that, according to the SIEF agreement, 'the Affiliate could use the [LoA] without additional payment'. The Claimant asked the Other Party to confirm this information.
8. On 31 May 2018, the Other Party explained that 'the SIEF agreement [did] detail the affiliate usage, which should [have been the Claimant's] reference point, as this [was] the legal position'. On the same day, the Claimant asked the Other Party for confirmation of the previous discussion. On the same day, the Other Party confirmed that 'the LoA purchased [allowed] for use within that banding'. The Other Party advised the Claimant to confirm this information with someone of the Claimant's staff who was 'well-versed in ECHA law'.
9. On 19 June 2018, The Claimant wrote that '[their] client [i.e. the non-EU manufacturer] has purchased the LOA of [the Substance] for [REDACTED]', and that '[the Affiliate] has also decided to make the [REACH] registration'. The Claimant then asked the Other Party to send them the joint submission name and token.
10. On 20 June 2018, the Other Party stated that they could provide the Claimant 'with costs per annex/tonnage band and a SIEF [agreement] for [the Affiliate] to join the registration'. Further, they added that the registration and the joint submission token issued to the non-EU manufacturer were 'specifically for them and [could not] be re-issued to a third party'. The Other Party asked the Claimant to indicate how they would like the Other Party to proceed.
11. On 21 June 2018, the Claimant reiterated that the non-EU manufacturer had an affiliate, and that, according to the SIEF agreement, 'the [A]ffiliate could also use the [LoA] without additional payment'. The Claimant asked the Other Party again to confirm the information. On the same day, the Other Party confirmed that 'what [the Claimant was] previously advised [was] correct', specifying that '[the non-EU manufacturer's] affiliates [could] share [their] registration and tonnage allowances'. However, issuing another token '[would require] another co-registration'. They again asked the Claimant to indicate how the Other Party should proceed.
12. On 22 June 2018, the Claimant asked the Other Party to confirm that they could 'use the [LoA] freely', but would need to pay for another token. The Claimant asked what the fee for the token was. On the same day, the Other Party tried to explain the situation again by giving an example and comparing the purchase of a LoA to the purchase of a car. If the Affiliate wanted 'to share [the non-EU manufacturer's] registration (car) that [would be] fine, but [the Other Party could not] supply another one without an additional SIEF and payment'. The Other Party stated that they would provide the Claimant with the cost proposal after the

Claimant had indicated their tonnage band to them.

13. On 25 June 2018, the Claimant concluded, based on the Other Party's previous email, that the Other Party meant that the non-EU manufacturer and the Affiliate '*could use the same registration [number]*'. The Claimant thought that '*ECHA couldn't accept this*', and that the explanation of the Other Party was not compatible with the SIEF agreement. The Claimant quoted a clause of the agreement and stated that, based on the agreement, '*the Affiliate could use the [LoA] freely*' if their tonnage band was not more '*than the one of [the non-EU manufacturer]*'. The Claimant stated that what the Other Party had previously said contradicted the SIEF agreement. The Claimant wrote that the quoted clause of the SIEF agreement was similar to other SIEF agreements. Further, according to the Claimant, other lead registrants would provide the joint submission name and token without additional cost.
14. On 25 June 2018, the Other Party wrote that the Claimant had an incorrect interpretation of the SIEF agreement and that the Other Party '*[would] not issue additional tokens without suitable payments and agreements*'. On the same day, the Claimant again asked what the fee for an additional token was, as they had not received such information from the Other Party. They also asked why the Other Party had not told already in May that they would charge for additional tokens. Concerning the SIEF agreement, the Claimant wrote they would again discuss it internally, adding that if the Other Party '*insist[ed] that [it was] incorrect [the Claimant would have] to forward [their] request to ECHA*'.
15. On 25 June 2018, the Other Party replied that they were '*waiting for [an internal] discussion to be resolved before issuing another quote*', but stated that '*[f]or guidance, this [would likely] be the same price and conditions as the previous quote*'.
16. On 29 June 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

17. As explained in section A, ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B.
18. The Claimant opened the negotiations by asking the Other Party to confirm that, in accordance with the SIEF agreement, the Affiliate of the non-EU manufacturer could use the LoA without an additional payment.⁶ The Claimant attempted repeatedly to receive the requested information from the Other Party.⁷ However, the Other Party did not make every effort to communicate in a consistent manner with the Claimant, changing their answers along the negotiations. In fact, in the beginning of the negotiations, the Other Party stated that '*[the] SIEF agreement [did] detail the affiliate usage*'⁸ and that '*[the] LoA purchased allow[ed] for use within that banding*'⁹, seemingly confirming the Claimant's interpretation of the SIEF agreement.
19. However, the Other Party subsequently provided different information, indicating that the registration and joint submission token issued to the non-EU manufacturer '*[were] specifically for them and [could not] be re-issued to a third party*', while offering to provide the Claimant '*with costs per annex/tonnage band and a SIEF for [the Affiliate] to join the registration*'.¹⁰ The Claimant replied by explaining again that, according to the SIEF agreement, '*[the Affiliate]*

⁶ The Claimant, 25 May 2018.

⁷ The Claimant, 31 May 2018, 19 June 2018, 21 June 2018 and 22 June 2018.

⁸ The Other Party, 31 May 2018.

⁹ The Other Party, 31 May 2018.

¹⁰ The Other Party, 20 June 2018.

could also use the [LoA] without additional payment'.¹¹ As a reply, the Other Party confirmed that 'what [the Claimant was] previously advised [was] correct', indicating also that '[the non-EU manufacturer's] affiliates [could] share [their] registration and tonnage allowances'.¹²

20. In order to act as a consistent and reliable negotiator, the Other Party should have been familiar with the content of the SIEF agreement and therefore able to answer clearly and unambiguously any questions asked by the Claimant. The Other Party changed their position on the interpretation of the SIEF agreement during the negotiations, and gave contradictory answers to the Claimant. This led to confusion in the negotiations between the parties.
21. Moreover, the Other Party failed to provide an explanation as to why the Claimant should pay for another token, even though the Claimant had noted that it would be in contradiction with the SIEF agreement.¹³ After the Claimant asked them to confirm the message of 21 June 2018, i.e. that the Affiliate '*could use the LOA freely but [would] need to*' pay for another token,¹⁴ the Other Party attempted to explain the SIEF agreement by comparing the purchase of a LoA to the purchase of a car, which both the non-EU manufacturer and the Affiliate could '*drive*' with '*no additional payment to [the Other Party]*'.¹⁵ However, when the Claimant explained that using the same registration number for different legal entities of the same non-EU manufacturer contradicted both the REACH registration requirements and the SIEF agreement,¹⁶ the Other Party merely replied that the Claimant's interpretation of the SIEF agreement was incorrect, without further justification on this or on the Claimant's arguments regarding the use of the same registration number.¹⁷ Therefore, the Other Party failed to make every effort to find a common understanding on the meaning of the data sharing agreement.

D. Conclusion

22. The Claimant made every effort to reach an agreement on access to the joint submission and the sharing of information, whereas the Other Party failed to do so.
23. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies specified in Annex II.

¹¹ The Claimant, 21 June 2018.

¹² The Other Party, 21 June 2018.

¹³ The Claimant, 25 June 2018.

¹⁴ The Claimant, 22 June 2018.

¹⁵ The Other Party, 22 June 2018.

¹⁶ The Claimant, 25 June 2018.

¹⁷ The Other Party, 25 June 2018.

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