

██████████  
Helsinki, 19 November 2018

*The Claimant*

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██████████  
██████████  
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*Represented by*

██████████  
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Copy to:  
*The Other Party*

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Decision number:

Dispute reference number:

Name of the substance (the 'Substance'):

EC number of the Substance:

██████████  
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██████████

**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')<sup>1</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>2</sup>.

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<sup>1</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, *OJ L 396*, 30.12.2006, p.1, as last amended.

<sup>2</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,

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 website<sup>3</sup>.

## **B. 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>.

## **C. 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.

The purpose of an inquiry under Article 26 REACH is for a potential registrant who has not pre-registered a substance to become aware of the studies which have been submitted and of the identity of those who have submitted the studies, so that they can contact them for data sharing. Where a potential registrant is already negotiating the studies that they need for registration with the existing registrants, an inquiry fulfils no practical purpose. Therefore, an inquiry is not necessary, if a potential registrant is already in contact with the existing registrants following a pre-registration.

Yours sincerely,

Christel Schilliger-Musset<sup>4</sup>

Director of Registration

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p.41.

<sup>3</sup> Available at <https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach>.

<sup>4</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.

## 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.
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

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 3 September 2018. The Other Party was asked to provide evidence on 11 September 2018 and a reminder was sent on 27 September 2018; however, they did not submit any evidence.
6. On 7 March 2018, the Claimant's representative emailed the Other Party to request the Letter of Access (LoA) for the substance. They requested *'the current status of registration, i.e. envisaged submission date, availability of LoA etc.'*, and asked *'[f]or which tonnage band is a registration planned and is an update possible?'*
7. On 19 April 2018, the Claimant's representative indicated that they had called and talked to the Other Party but *'the line was disconnected.'* They said that they wanted to thank the Other Party for their *'time today and the information.'* They shared their contact information *'[i]n order to set the communication'* and asked the Other Party to *'respond with a short email'*. The same day, the Other Party sent the Substance Identity Profile (SIP), the substance's identified uses, and the *'calculation of the cost of the LOA for the tonnage band [REDACTED] ([there] should be [REDACTED] or [REDACTED] companies to register the substance)'*. They said that *'[t]he cost of the LOA is the same for the two tonnage bands.'* The Other Party stated that they were *'working on the validation of read across with [another substance].'*
8. On 30 May 2018, the Claimant's representative asked whether there was any news regarding substance registration and the process to obtain the LoA, as their client *'would*

like to register the substance within the next months (substance identity analytics started).’ The same day, the Other Party stated that they ‘registered the substance for the tonnage band [REDACTED] t / year. To register after 31st May 2018 [the Claimant] must apply to ECHA. ECHA will decide according to the composition of [the Claimant’s] substance if it can be related to [the Other Party’s] registration. ECHA will then ask [the Claimant] to contact [the Other Party] to make a joint submission (Inquiry procedure). It would have been easier for [the Claimant] to register before May 31, 2018 if [the Claimant’s] substance had been pre-registered.’

9. On 29 June 2018, the Claimant’s representative responded to the Other Party’s remark related to the need for an inquiry. They noted that their client had not intended to register by the end of May and was aware of the need for an inquiry; however, ‘ECHA released the note that Pre-registration numbers are still valid for performing a registration.’ They asked the Other Party to provide them with ‘a Joint Submission Agreement and details [on] how to perform Payment’.
10. On 11 July 2018, the Claimant’s representative emailed again to request the LoA, and requested that ‘[i]f the relevant documents are under preparation, please indicate an estimated date when these will be available.’
11. On 3 August 2018, the Claimant’s representative asked, following their ‘telephone call last Friday (July 24th)’, for ‘the status of the draft agreement for LoA [that the Other Party] promised.’ They noted that if they did not receive anything by the ‘end of next week i.e. August 10<sup>th</sup>’, they would ‘have to rate it as hindrance of market access’ and would contact ECHA.
12. On 30 August 2018, the Claimant’s representative stated that they would be filing a dispute with ECHA due to the lack of response from the Other Party ‘since our last call (27. July 2018) and the message sen[t] afterwards (3. August 2018).’ They noted that they would ‘still welcome [the Other Party] to submit the data sharing agreement and notices on how to obtain the LoA.’
13. On 3 September 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, for the tonnage band [REDACTED].

### **C. Assessment**

14. As explained in section A., ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B.
15. On 19 April, the Other Party sent the SIP, the LoA costs and the uses covered by the registration, and added that they were currently working on the validation of the read across with another substance. Therefore, the Claimant was left with the expectation that more information would be forthcoming on when the read across would be completed, in order to have all the final details about the registration dossier. However, after waiting until 30 May, when the Claimant asked the Other Party about the status of the registration, they were told that they had to make an inquiry if they wanted to register after 31 May. So the Other Party again left the Claimant in a position where their registration would be delayed. Then, following their claim that an inquiry would be necessary before continuing any negotiation with them after the deadline, the Other Party stopped replying to the Claimant.
16. Although that argument may be valid in light of Article 26(1) of REACH, both parties still have to make every effort to find an agreement and understand whether an inquiry is necessary. In the case at hand, however, it appears that the Other Party failed to make such effort and instead caused the negotiations to be delayed and be extended beyond the deadline. To make every effort, the Other Party could have responded to the Claimant’s

counter-argument of 29 June that the Claimant's pre-registration number was valid for registration with ECHA and engaged in a discussion on whether an inquiry was required.

17. The Claimant repeatedly sent reminders regarding the LoA. Although there were some breaks in communications from the Claimant—for example, between the communications of 19 April and 30 May, and then from 30 May to 29 June—these do not outbalance the delay caused by the Other Party and their subsequent lack of response.
18. By refusing to reply or to discuss the need for an inquiry after the deadline, the Other Party prevented any substantive negotiations, thereby failing to comply with Article 30(1) of the REACH Regulation.

#### **D. Conclusion**

19. Based on the above, ECHA concludes that the Claimant made every effort to progress in the data sharing negotiations by continuing to attempt to contact the Other Party and by requesting the LoA. Conversely, the Other Party did not make every effort to progress the negotiations and reach an agreement with the Claimant.
20. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies specified in Annex II.

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