

[REDACTED]  
Helsinki, 11 July 2018

*The Claimant*

[REDACTED]

*Represented by*

[REDACTED]

Copy to:  
*The Other Party*

[REDACTED]

*Represented by*

[REDACTED]

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

## **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')<sup>1</sup> and Article 5 of the Commission Implementing Regulation (EU) 2016/9

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<sup>1</sup> 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,

on joint submission of data and data-sharing in accordance with REACH ('Implementing Regulation 2016/9')<sup>2</sup>.

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 Annex 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. 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<sup>4</sup>

Director of Registration

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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, 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 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.
3. Making every effort means that 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 the 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 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 to reply to the requests of the counter party regarding information or other relevant documentation necessary to move forward with the negotiations in a fair, transparent and non-discriminatory way.

### B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 10 April 2018. The Other Party did not provide evidence upon ECHA's request.
6. Between February 2013 and July 2013, several emails were exchanged between the Other Party, the Claimant and other pre-SIEF members. In these emails, several issues regarding the joint submission were discussed (e.g. lead registrant appointment, substance identity, preparation of common parts of dossier).<sup>5</sup>
7. On 26 July 2013, the Other Party informed that the dossier for the substance was submitted to ECHA and that it was '*open for the joint submission*'. The Other Party also provided some preliminary information regarding the dossier's technical issues and the *agreement*' (A). Finally, the Other Party informed that the A would be sent to interested potential registrants and after '*the signature of A*', '*all documents useful to support the registration*', '*a copy of the joint registration dossier including GSU and CSR*', '*the joint submission name and the token*' and '*a formal [Letter of Access, would] be provided*.'<sup>6</sup>
8. On 29 May 2017, the Other Party apologised for the delay in replying to the Claimant and sent information regarding the substance identity profile and the costs to join the joint

<sup>5</sup> Other Party, Claimant and Other pre-SIEF members; 21 February 2013 to 9 July 2013.

<sup>6</sup> Other Party; 26 July 2013.

submission for the tonnage bands [REDACTED] and [REDACTED].<sup>7</sup>

9. On 13 November 2017, the Claimant informed the Other Party that they would like to submit their registration as soon as possible and requested the 'documents of the Letter of Access' and the invoice in order to proceed.<sup>8</sup>
10. On 22 March 2018, the Claimant reminded the Other Party that they needed to register the substance as a member and that the lead registrant should provide all the necessary information. They also informed that, since there had been no answer after several communications asking for the substance identity profile and the Letter of Access, they would submit a data-sharing dispute to ECHA on 3 April 2018, unless the Other Party would provide the requested information.<sup>9</sup>
11. On 10 April 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 (for a tonnage band of [REDACTED]).

### C. Assessment

12. As explained in section A., ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B.
13. 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. The Claimant requested the Letter of Access on 13 November 2017 and sent a reminder on 22 March 2018. The Other Party did not provide the Letter of Access to the Claimant despite of the request and the reminder. As a result, the Other Party did not make every effort to reach an agreement.
14. Moreover, making every effort to reach an agreement means that an existing registrant also needs to address other requests by a potential registrant.
15. ECHA notes that the Other Party made an effort to reach an agreement with the Claimant in July 2013, when they informed that their dossier was submitted to ECHA, invited the Claimant to join the joint submission and informed that they would provide the [REDACTED] A and all the necessary documents to join the joint submission after the Claimant's signature. Additionally, the Other Party also made efforts to reach an agreement with the Claimant when, four years later, they provided information regarding the substance identity profile and the costs to join the joint submission for the tonnage bands [REDACTED] and [REDACTED].
16. However, when the Claimant contacted the Other Party and requested to have the Letter of Access and the invoice to progress with their registration, the Other Party did not provide any answer. Moreover, after the Claimant's reminder four months later, the Other Party still did not reply.
17. The Claimant made every effort to reach an agreement as they tried to start the negotiations by contacting twice the Other Party and by making a clear request to have the Letter of Access and invoice as soon as possible. However, without a reply from the Other Party it was not possible to progress in the negotiations and therefore, it was not possible to make any more effort to find an agreement with the Other Party. In the light of the above, the Claimant made every effort to reach an agreement.
18. Although in the beginning of the negotiations the Other Party made efforts to reach an

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<sup>7</sup> Other Party; 29 May 2017.

<sup>8</sup> Claimant; 13 November 2017.

<sup>9</sup> Claimant; 22 March 2018.

agreement, the failure to provide the Letter of Access weighs heavier in the effort assessment. Therefore, the Other Party failed to make every effort to reach an agreement.

**D. Conclusion**

19. The Claimant made every effort to reach an agreement on the access to the joint submission and the sharing of information whereas the Other Party failed to make such effort.
20. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies specified in Annex [REDACTED]

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