

3 December 2021

*The Claimant*

[REDACTED]

Copy to:

*The Other Party*

[REDACTED]

**Sent via REACH-IT**

Decision number:

Dispute reference number:

Name of the substance (the 'Substance'):

EC number of the Substance:

[REDACTED]

**DECISION ON A DISPUTE RELATED TO THE SHARING OF DATA**

**A. Decision**

Based on Article 27(6) of Regulation (EC) No 1907/2006 ('REACH Regulation')<sup>1</sup> and Article 5 of 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>,

**ECHA grants the Claimant permission to refer to information requested from the Other Party for the purpose of a registration under the REACH Regulation. However, this decision is subject to the receipt by ECHA of the proof that the Claimant has paid the Other Party a share of the costs incurred pursuant to Article 27(6) of the REACH Regulation ('proof of payment'), within two months from the notification of the present decision, i.e. by 3 February 2022.**

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

<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, 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.

The list of studies covered by the present decision, along with copies of the (robust) study summaries, can be found in Annexes II and III, respectively. However, **the Claimant cannot make use of this permission to refer** to submit a registration dossier for the Substance **before submitting to ECHA a proof of payment and before receiving from ECHA an acknowledgment of receipt.**

Provided that the Other Party makes the full study report available to the Claimant, the Other Party shall have a claim on the Claimant for an equal share of the cost it has incurred, which shall be enforceable in the national courts.

**If the Claimant does not provide ECHA with proof of payment within two months from the notification of the present decision,** ECHA will issue a decision revoking the present decision. In such case, the Claimant may continue negotiating to reach an agreement with the Other Party. Should these subsequent negotiations fail, the Claimant can submit a new dispute to ECHA.

This decision will be published in an anonymised version on ECHA's website<sup>3</sup>.

## **B. Observations**

The present decision may not cover all the Claimant's information needs under Annex [REDACTED] of the REACH Regulation.

Despite the present decision, both parties are still free to reach a voluntary agreement. ECHA strongly encourages the parties to negotiate further in order to reach an agreement that will be satisfactory for both parties.

Instructions to the Claimant on how to submit a registration dossier making use of the permission to refer are provided in Annex IV.

## **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. Further details, including the appeal fee, are set out at <http://echa.europa.eu/web/guest/regulations/appeals>.

Authorised<sup>4</sup> by Minna Heikkilä, Head of Legal Affairs

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

## **Annex I: REASONS FOR THE DECISION**

### **A. Applicable law**

1. In a dispute 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 Implementing Regulation 2016/9). According to Article 27(6) of the REACH Regulation and Article 3(2) of Implementing Regulation 2016/9, ECHA may grant 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 transparent, fair 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 Implementing Regulation 2016/9.
3. Specifically, Article 27(3) of the REACH Regulation and Article 2 of Implementing Regulation 2016/9 provide for the requirement for data and cost sharing to be transparent. Article 2(1)(a) and (2) of Implementing Regulation 2016/9 require a previous registrant to provide to a potential registrant, upon request, an *"itemisation of data to be shared, including the cost of each data item, a description indicating the information requirements in the REACH Regulation to which each cost corresponds and a justification of how the data to be shared satisfies the information requirement."* Under the last subparagraph of Article 2(2) of Implementing Regulation 2016/9, the previous registrant is expected to provide this information to the potential registrant *"without undue delay."* The previous registrant is thus required to provide, upon request from a potential registrant, clear and comprehensible explanations on which information is to be shared and on what basis, as well as how the relevant costs are determined and shared among registrants.<sup>5</sup>
4. The parties 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. In doing so, each party must clearly state his or her requests of information, and ensure that the other party has had enough time to provide an answer before concluding that the negotiations have failed.

### **B. Summary of facts**

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 29 October 2021 and by the Other Party on 15 November 2021.
6. During the negotiations most e-mail messages were exchanged between the Other Party, on one side, and a consultant acting on behalf of the Claimant, on the other side. For the sake of simplicity, however, no distinction is made below between the Claimant and the Claimant's representative, and only the Claimant is referred to as taking part in the exchange.
7. On 15 October 2019, the Claimant first contacted the Other Party to request the Substance Identity Profile of the Substance, a copy of the "SIEF agreement", costs for the Letters of Access ("LoA") for [REDACTED] and [REDACTED] and confirmation of the information provided by the lead registrant.<sup>6</sup> The Other Party informed the Claimant on 18 October 2019 that it was still in the process of upgrading its registration dossier from [REDACTED] to [REDACTED] and that

<sup>5</sup> See Cases A-014-2018 to A-021-2018, Decision of the Board of Appeal of 23 July 2020, paragraph 46.

<sup>6</sup> E-mail from Claimant, 15 October 2019.



it hoped to complete this process in December.<sup>7</sup> The Claimant asked if the [REDACTED] costs were available, but the Other Party replied that they were not; the Other Party promised to provide these as soon as they were available.<sup>8</sup>

8. On 5 December 2019 and 3 January 2020, the Claimant sent reminders to the Other Party to enquire about the fees for the [REDACTED] and [REDACTED] LoAs.<sup>9</sup> A series of e-mails were exchanged consisting of update requests and holding replies between 6 January 2020 and 19 January 2020.
9. On 21 January 2020, the Other Party confirmed the LoA fees for both tonnage bands.<sup>10</sup> On the same day, the Claimant requested an itemised breakdown of the costs, including the cost of the Chemical Safety Report ("CSR").<sup>11</sup> The Claimant repeated its request on 11 February 2020.<sup>12</sup> The Other Party provided a breakdown on 20 February 2020.<sup>13</sup>
10. On 22 February 2020, the Claimant requested clarification for what it saw as a number of inconsistencies in the breakdown that had been provided.<sup>14</sup> The Other Party responded the following day.<sup>15</sup> On 24 February 2020, the Claimant confirmed that it only needed the Annex [REDACTED] data, as it had already purchased access for the Annex [REDACTED] data and requested a breakdown of the Annex [REDACTED] upgrade costs including all testing work and cost of the CSR.<sup>16</sup> The Other Party provided the information on 27 February 2020.<sup>17</sup>
11. Over the course of 2020, the parties exchanged e-mails every few months. Typically, the Claimant would reiterate its interest in upgrading its registration, request the updated/revised fees together with a breakdown of the costs and request clarification for certain cost items.
12. On 16 December 2020, four months after the last exchange with the Other Party, the Claimant indicated that it wished to restart cost sharing negotiations. It noted that there was a new registrant in the [REDACTED] bracket and therefore asked the Other Party to provide the revised costs to upgrade its registration. It further requested a breakdown of the upgrade costs across the different areas of the registration.<sup>18</sup>
13. The Other Party sent a holding reply on 8 January 2021.<sup>19</sup> On 18 January 2021, the Other Party informed the Claimant of the new LoA update fee based on three registrants, but did not include the requested breakdown.<sup>20</sup>
14. On 6 May 2021, the Claimant contacted the Other Party to ask whether the updated fee quoted in January was still accurate, which the Other Party confirmed on 8 May 2021.<sup>21</sup> On 10 May, the Claimant noted that the Other Party did not include access to the CSR and therefore asked whether it would provide access to the robust study summaries in IUCLID

<sup>7</sup> E-mail from Other Party, 18 October 2019

<sup>8</sup> E-mails from Claimant, 18 and 29 October 2019; e-mail from Other Party, 30 October 2019.

<sup>9</sup> E-mails from Claimant, 5 December 2019 and 3 January 2020.

<sup>10</sup> E-mail from Other Party, 21 January 2020.

<sup>11</sup> E-mail from Claimant, 21 January 2020.

<sup>12</sup> E-mail from Claimant, 11 February 2020/

<sup>13</sup> E-mail from Other Party, 20 February 2020.

<sup>14</sup> E-mail from Claimant, 22 February 2020.

<sup>15</sup> E-mail from Other Party, 23 February 2020.

<sup>16</sup> E-mail from Claimant, 24 February 2020.

<sup>17</sup> E-mail from Other Party, 27 February 2020.

<sup>18</sup> E-mail from Claimant, 16 December 2020.

<sup>19</sup> E-mail from Other Party, 8 January 2021.

<sup>20</sup> E-mails from Other Party, 8 and 18 January 2021.

<sup>21</sup> E-mail from Claimant, 6 May 2021; e-mail from Other Party, 8 May 2021.

format in order to aid the Claimant in its preparation of the CSR. The Other Party confirmed it would.<sup>22</sup>

15. On 28 June 2021, the Claimant requested a breakdown of the joint registration costs. Regarding the *"SIEF management and dossier preparation costs"*, in particular, the Claimant noted that these *"were quite high for the tonnage band of the dossier and the age of the joint submission"* and thus asked the Other Party if they could provide additional information regarding them. Finally, the Claimant asked the Other Party to confirm if the sharing of the data was based on a 100% reimbursement of the cost or, alternatively, whether any reduction had been included to avoid data ownership disputes.<sup>23</sup> No further communication took place between the parties until 29 October 2021.
16. On 29 October 2021, the Claimant notified the Other Party that it was placing a data sharing dispute with ECHA.<sup>24</sup> The dispute was submitted to ECHA on the same day.

### C. Assessment

17. As explained in section A, ECHA is called upon to determine whether the parties complied with their obligations related to the sharing of data and data costs in the negotiations outlined in section B.
18. In that context, the Agency will assess the first criterion laid down in Article 2(2) of Implementing Regulation 2016/9, namely whether the agreement was negotiated in accordance with the transparency requirement.
19. In addition, when carrying out its assessment, the Agency must pay due regard to all individual actions and communications of the parties as well as the development of the negotiations over time. Finally, the Agency's assessment centres upon those elements on which the parties could not agree during their negotiations, and which therefore led to the filing of the case.
20. In the present case, the Claimant informed the Other Party that they had failed to provide an acceptable explanation for all of the costs related to the LoA fee for upgrading its registration to [REDACTED].<sup>25</sup> The Agency will therefore verify the parties' compliance with their data sharing obligations against the requirements set out above, namely whether the Other Party provided the Claimant with the cost itemisation *"without undue delay"* as required by Article 2(2) of Implementing Regulation 2016/9.
21. As shown in Section B above, although the discussions and negotiations between the parties took place over a two year period, they were essentially a succession of enquiries by the Claimant regarding LoA fees, number of registrants and requests for cost itemisation. The last round, prior to the submission of the dispute, started on 6 May 2021, when the Claimant requested confirmation for the LoA fee for upgrading its registration to [REDACTED]. Although the price had remained unchanged since the previous round of discussions that took place between 16 December 2020 and 18 January 2021, the Other Party had not, at that point, provided a breakdown of the costs related to the updated LoA fee.
22. The Other Party had provided breakdowns relating to certain cost elements and responded to the Claimant's queries in previous discussions (see paragraphs 7-11 above). However, the LoA fee in question had changed when the Claimant contacted the Other Party on 16

<sup>22</sup> E-mail from Claimant 10 May 2021; e-mail from Other Party, 12 May 2021.

<sup>23</sup> E-mail from Claimant, 28 June 2021.

<sup>24</sup> E-mail from Claimant, 29 October 2021, including attachment letter dated 26 October 2021.

<sup>25</sup> *Ibid.*

December 2020. The Claimant therefore requested a breakdown of the then current joint registration costs and specifically requested further information regarding two cost elements, namely i) the "*SIEF management*" costs and ii) the "*dossier preparation*" costs. It further requested confirmation of the basis for the data sharing, i.e. 100% reimbursement of costs or whether any reduction had been included to avoid data ownership disputes.

23. None of these requests were responded to by the Other Party between 28 June 2021 (the date of the Claimant's email) and 29 October 2021 when the dispute was submitted to ECHA.
24. It follows that the Other Party did not comply with the requirement of providing the itemisation of costs to the Claimant "*without undue delay*", as required by Article 2(2) of Implementing Regulation 2016/9.
25. As a result, the breach of the transparency obligation by the Other Party made it impossible for the Claimant to constructively engage in the discussion, and for both parties to achieve a data sharing agreement for the tonnage band of interest to the Claimant in a timely fashion.
26. This case refers to information requested to the Other Party by the Claimant for an upgrade of its registration to the [REDACTED] tonnage band.

#### **D. Conclusion**

27. The Other Party failed to comply with its obligations with a view to achieve an agreement on the sharing of information and associated costs, as provided for by Article 2(2) of Implementing Regulation 2016/9.
28. Therefore, ECHA grants the Claimant permission to refer to the studies specified in Annex II, subject to the receipt by ECHA of the proof that the Claimant has paid the Other Party a share of the costs incurred. This proof of payment must be submitted to ECHA by 3 February 2022. In case it is not submitted by the indicated date, the present permission to refer will be revoked.