[redacted]

11 July 2023

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

Represented by

[redacted]

Sent via REACH-IT

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 SHARING OF DATA

A. Decision

ECHA does not grant a permission to refer to the information requested from the Other Party.

This decision is adopted under Article 27(6) 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].

[1] 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.

[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.

[redacted]

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

This decision will be published in an anonymised version on ECHA's website[3].

a. Recommendation

ECHA advises the parties to negotiate in order to reach an agreement that will be satisfactory for both parties.

[redacted] According to the REACH Regulation, any (robust) study summaries submitted more than 12 years previously can only be used for the purposes of registration. Furthermore, the provision by ECHA of copies of (robust) study summaries does not provide ownership rights on this data.

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.

Authorised[4] by Minna Heikkilä, Head of Legal Affairs

[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 ECHA's internal decision-approval process.

[redacted]

Annex I: REASONS FOR THE DECISION

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 parties' efforts 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 access to the joint submission 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). In such case, ECHA grants the claimant a permission to refer to the requested studies in the dossier of the previous registrant(s) for the purposes of registration of the same substance or an update thereof (tonnage band upgrade).

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.

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. Article 25(3) of the REACH Regulation establishes that any study summaries or robust study summaries of studies submitted in the framework of a registration at least 12 years previously can be used for the purposes of registration by another manufacturer or importer. This applies also for read across or grouping adaptations.[5]

[5] See section 3.1.4.1 of the Guidance on Data Sharing, available at https://echa.europa.eu/guidance-documents/guidance-on-reach.

[redacted]

B. Summary of facts

1. This summary of facts is based on the documentary evidence submitted by the Claimant on 23 May 2023 and by the Other Party, represented by a consultant, on 19 June 2023.

2. The negotiations between the parties started in November 2022, after the Claimant, a co-registrant in the joint submission for the Substance, requested access to the data owned by the Other Party (consultant) "*[f]or the purpose of a* [redacted] *registration*".[6]

3. When asked to clarify the request, the Claimant noted that the Substance "*is a* [redacted] *substance*", thus they "*would need access to the robust study summaries of the studies covering the data requirements* [redacted] *for the purpose of EU-REACH*".[7] The Claimant added they would require the data for "*both EU-reach and UK-reach*".[8]

4. After some exchanges, the Other Party (consultant) noted they had "*an amendment to a data sharing agreement to cover GB REACH*" and that they had applied it to the "*EU read across data sharing agreement template to form a consolidated DSA covering EU and GB REACH*". They promised that once that amendment was approved by their client, the agreement would be sent to the Claimant for review.[9]

5. After sending a reminder and communicating their disappointment with the delay in receiving the draft data sharing agreement,[10] the Claimant asked the Other Party for "*the LoA fee for an upgrade to the highest tonnage band* [redacted]".[11] The Other Party asked whether the Claimant wished "*to get access to the [Substance] data in the lead dossier*".[12] The Claimant reiterated their initial request for "*access to the RSS of the lead dossier for the purpose of read across, starting with EU and UK later*".[13]

6. On 23 May 2023, the Claimant submitted a claim under Article 27 of the REACH Regulation concerning the failure to reach an agreement on the sharing of information with the Other Party. In the submission, the Claimant noted they sought from the Other Party "*a data sharing agreement including robust study summaries in the highest tonnage band for the purpose of read across*".

C. Assessment

7. As explained in section A, ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B.

8. At the beginning of the negotiations, the Claimant asked for the data in view of a read across adaptation for registration of another substance. After some discussion, the Claimant changed the request, referring to a tonnage band upgrade on the email of 9 May 2023. However, when the Other Party replied, they again reiterated their wish to obtain the data for the purposes of read across for registration of another substance (as attested by the messages described in paragraphs 2 to 5 of section B).

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[6] E-mail from the Claimant, 04/11/2022.
[7] E-mail from the Claimant, 07/11/2022.
[8] E-mail from the Claimant, 09/11/2022.
[9] E-mail from the Other Party, 31/01/2023.
[10] E-mails from the Claimant, 08/02/2023, 09/02/2023.
[11] E-mail from the Claimant, 09/05/2023.
[12] E-mail from the Other Party, 11/05/2023.
[13] E-mail from the Claimant, 11/05/2023.

[redacted]

9. A permission to refer can only be given pursuant to Article 27(6) of the REACH Regulation for the purposes of the registration of the same substance or an update thereof (tonnage band upgrade). Since the Claimant seeks access to data for the purposes of a read across adaptation, their request does not fall within the scope of this provision. Consequently, ECHA has no competence to grant the Claimant access to the Other Party's data for such purposes under Article 27(6) of the REACH Regulation.

10. Access to data for the purposes of a read across adaptation may be obtained pursuant to Article 25(3) of the REACH Regulation, provided that the conditions set out in that provision are fulfilled.

D. Conclusion

11. ECHA does not grant the Claimant permission to refer to the requested studies.