ECHA
EUROPEAN CHEMICALS AGENCY

21 February 2022

The Applicant

Copy to:
The Other Party

Sent via REACH-IT

Decision number:
Application reference number:
Name of the Substance:

EC number of the Substance:

DECISION ON AN APPLICATION FOR A PERMISSION TO REFER TO INFORMATION SUBMITTED BY A PREVIOUS REGISTRANT

A. Decision

Based on Article 30(3) of Regulation (EC) No 1907/2006 ('REACH Regulation')[2] 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')[3],

ECHA grants the Applicant permission to refer to information involving tests on vertebrate animals requested from the Other Party for the purpose of a registration under the REACH Regulation.

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

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.

[1]

[2] 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.

[3] 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.

This decision will be published in an anonymised version on ECHA's website[4].

B. Observations

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.

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

The present decision may not cover all the Applicant's information needs under Annexes ███ ████ of the REACH Regulation. In particular, with the present decision ECHA grants a permission to refer only to studies involving tests on vertebrate animals.

Instructions to the Applicant 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[5] by Minna Heikkilä, Head of Legal Affairs

[4] Available at https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach.

[5] 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 and Decision of the Board of Appeal

1. In its Decision of [redacted] in Case [redacted], [redacted], the Board of Appeal decided on an action initiated by the Applicant against ECHA's Decision [redacted] of [redacted] regarding the application for a permission to refer to data, filed by the Applicant in the present case. The Board of Appeal annulled the contested decision and remitted the case to ECHA for further action.

2. The Decision of the Board of Appeal indicated the need to examine the substantive merits of the application for a permission to refer and to hear the Other Party.[6] It further provided '*for the Agency to determine, in accordance with Article 30(3) of the REACH Regulation and Article 5(1) of Implementing Regulation 2016/9, whether the parties complied with their obligations, including whether the [Applicant] made requests and raised objections vis-à-vis [the Other Party] and, if so, whether [the Other Party] complied with the requirements of fairness, transparency and non-discrimination following those requests and objections*'[7]. Finally, the Decision of the Board of Appeal provided for the assessment to take into account all the exchanges which took place between the Applicant and the Other Party from their initial contacts in 2010 until the failure of their negotiations in December 2019.[8]

3. The requirements of fairness, transparency and non-discrimination are first laid down in Article 30(1) of the REACH Regulation, concerning the sharing of information between a participant in a Substance Information Exchange Forum ('SIEF') and the owner of a study involving tests on vertebrate animals. Such requirements are further defined in Articles 2 and 4 of Implementing Regulation 2016/9, as recalled by Article 5(1) of the same Regulation.

4. Specifically, Article 30(1) 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(2) of Implementing Regulation 2016/9 requires a previous registrant of a substance for which a data sharing agreement has already been concluded to provide a potential registrant, upon request, with an itemisation of the data to be shared and of administrative costs related to it. According to Article 2(1)(a), the itemisation of data includes '*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*'. According to Article 2(1)(b), the itemisation of administrative costs consists of '*the itemisation and justification of any cost of creating and managing the data-sharing agreement and the joint submission of information between registrants of the same substance as required by [the REACH Regulation] [...] applicable for that data-sharing agreement*'.

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Applicant on 20 December 2019 and by the Other Party on 16 November 2021. Part of the documentary evidence submitted by the Other Party consists of records of e-mail communications taking place after the submission of the application, and it has therefore not been taken into account in the assessment.

6. On 12 November 2010, the Applicant received a message sent on behalf of the [redacted] ('First Consortium Manager'), concerning the substance [redacted], [redacted] The First Consortium Manager appeared

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[6] Decision of the Board of Appeal of ECHA of [redacted], Case [redacted] paragraph 59.

[7] *Ibid.*, paragraph 60.

[8] *Ibid.*, paragraph 61.

to act as a coordinator of the SIEF for that substance, and the Applicant was listed in the message as a SIEF member holding a pre-registration. In that context, the First Consortium Manager provided a revised Substance Identification Profile ('SIP').[9]

7. On 14 November 2010, in reaction to the above message, the Applicant confirmed to the First Consortium Manager that the substance manufactured or imported by the Applicant fitted in the revised SIP, and requested a data sharing agreement as soon as possible.[10]

8. On 17 May 2017, the Applicant received a new message concerning the above-mentioned substance from [redacted] ('Second Consortium Manager'), who appeared to act as SIEF coordinator at that time. The Applicant was again identified as holding a pre-registration of the substance and was informed that ECHA, following a review of the substance identification, had re-qualified the substance as [redacted] (the Substance) and had assigned a new chemical identifier to it [redacted]. The Second Consortium Manager advised that the lead registrant of the Substance was the Other Party, and invited SIEF members to get in touch with the Second Consortium Manager if they required a Letter of Access ('LoA') to the joint dossier.[11]

9. On 20 November 2019, the Applicant contacted, with separate messages, the Other Party,[12] the First Consortium Manager[13] and [redacted] ('Third Consortium Manager'),[14] signalling the Applicant's interest in registering the Substance in the [redacted] tonnage band. The Applicant asked the SIP and the draft data sharing agreement. Finally, the Applicant stated that its intention was to proceed with the registration by taking advantage of '*the delayed deadline (30 December 2019) established by the second implementing regulation*[15]'.

10. On 21 November 2019, the Applicant wrote again to the Other Party, reiterating the intention to register under Article 30 of the REACH Regulation and Article 3 of Implementing Regulation 2019/1692.[16]

11. On 22 November 2019, the Third Consortium Manager reacted to the message from the Applicant and provided the requested SIP and the cost of the LoA.[17]

12. On 25 November 2019, the Applicant requested the Other Party to provide a '*properly itemized datasharing agreement*'. As part of the request, the Applicant asked '*an itemisation of all incurred costs*' and invited the Other Party to answer in one week's time. The Applicant flagged the need to process the request promptly due to the upcoming Christmas holidays and the end-of-year deadline.[18]

13. On that same day, the Other Party indicated the contact person within the Third Consortium Manager that would conduct the negotiations on the Other Party's behalf.[19] From this point

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[9] E-mail message of the First Consortium Manager of 12 November 2010.
[10] E-mail message of the Applicant of 14 November 2010.
[11] E-mail message of Second Consortium Manager of 17 May 2017.
[12] E-mail message of the Applicant of 20 November 2019, 16:07.
[13] E-mail message of the Applicant of 20 November 2019, 15:41.
[14] E-mail message of the Applicant of 20 November 2019, 15:25.
[15] ECHA understands that the Applicant referred to Article 4 of Commission Implementing Regulation (EU) 2019/1692 of 9 October 2019 on the application of certain registration and data-sharing provisions of Regulation (EC) No 1907/2006 of the European Parliament and of the Council after the expiry of the final registration deadline for phase-in substances, OJ L 259, p.12.
[16] E-mail message of the Applicant of 21 November 2019.
[17] E-mail message of the Third Consortium Manager of 22 November 2019.
[18] E-mail message of the Applicant of 25 November 2019, 12:07.
[19] E-mail message of the Other Party of 25 November 2019, 13:08.

onwards, for the sake of simplicity, both the Other Party and the Third Consortium Manager will be referred to as 'the Other Party'.

14. On 28 November 2019, the Applicant confirmed its interest in the purchase, reminded to the Other Party the *'delayed deadline'* of 30 December 2019, by which the Applicant understood the agreement should be reached in accordance with Implementing Regulation (EU) 2019/1692. Finally, the Applicant informed the Other Party that the Applicant would be unavailable as from 20 December 2019.[20]

15. As part of the exchange, the Other Party made available to the Applicant a draft data sharing agreement for the substance .[21] This included provisions on the sharing of costs among SIEF participants based on, *inter alia*, their respective tonnage bands, possible opt-outs, the allocation of costs among affiliates of a same participant and among registrants represented by a same only representative or third party representative.[22]

16. On 4 December 2019, the Applicant reiterated its request for a complete itemisation of data in accordance with Implementing Regulation 2016/9.[23] On the same day, the Other Party provided a document with a cost breakdown.[24] This consisted of a first table entitled *'Data costs'*, listing the information requirements addressed by the data, the Annex of the REACH Regulation from which each information requirement stemmed, whether the study was *'required'* or *'waived'* and the cost associated to each information requirement. A second table, entitled *'Sweat equity and consortium support costs'*, featured additional cost items and figures for *'Total Sweat Equity Costs for 11 members'* and *'Consortium Support costs to 31 May 2018'*.[25]

17. Together with the cost breakdown document, a so-called *'cost sharing process document'* was provided.[26] This consisted of a general explanation of the principles for the calculation of study and administrative costs and their division among LoA applicants, the conditions of the sale of LoAs and the process to obtain one. The document did not provide the actual number of registrants sharing the costs, nor their respective tonnage bands or whether they relied fully or partially on the jointly submitted data. At the opposite, it was stated that, as of 2018, the number of LoA applicants was still uncertain and that further information thereon would be provided *'following the May 2018 registration deadline'*. The LoA cost for each legal entity would be made available by the consortium manager upon request.[27]

18. On 10 December 2019, the Applicant pointed out to the Other Party that the provided breakdown did not allow to extrapolate the LoA value communicated previously and, in essence, to understand how the LoA cost was calculated. The Applicant requested *'a cost breakdown with all cost items expressed in such a way to arrive, after their sum, to the final requested amount'*.[28]

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[20] E-mail message of the Applicant of 28 November 2019, 09:59.

[21] E-mail messages of the Other Party of 29 November 2019, 10:17 and 10:20, and 3 December 2019; e-mail messages of the Applicant of 29 November 2019, 10:21 and 14:00, and 4 December 2019.

[22] Document *'Contract : Substance:* , 20 December 2019.

[23] E-mail message of the Applicant of 4 December 2019.

[24] E-mail message of the Other Party of 4 December 2019.

[25] Document *Cost and income reconciliation to 31 May 2018'*.

[26] E-mail message of the Other Party of 4 December 2019.

[27] Document *'Letters of Access from*

[28] E-mail message of the Applicant of 10 December 2019.

19. On 17 December 2019, the Applicant sent a first reminder of the request, inviting the Other Party to react in two days.[29]

20. On 19 December 2019, the Applicant sent a second reminder and announced its intention to submit an application for a permission to refer to data in case of failure by the Other Party to address the Applicant's request.[30]

21. On that same day, the Other Party acknowledged the Applicant's request for '*a more detailed breakdown of the costs contributing to the LoA fee*' but informed that the requested information could be made available only at the end of January.[31]

22. On 20 December 2019, the Applicant insisted that receiving a proper itemisation of costs was a precondition for the conclusion of the data sharing agreement, and that waiting until January would not be acceptable in light of the '*delayed deadline*' of 31 December 2019, by which the Applicant understood that the agreement should be reached in accordance with Implementing Regulation (EU) 2019/1692. The Applicant informed that an application for a permission to refer to data would be filed on the same day.[32]

23. On the same day, the Applicant submitted to ECHA its application for a permission to refer to data.

C. Assessment

24. 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.

25. In this context, ECHA must assess the parties' compliance with the criterion laid down in Article 2 of Implementing Regulation 2016/9, namely whether the agreement was negotiated in accordance with the transparency requirement.[33]

26. According to the reasoning set out in the Decision of the Board of Appeal of 22 June 2021, regard should first be paid to the initial exchanges occurred back in 2010. At the time, the Applicant requested a data sharing agreement,[34] presumably with a view to join the submission for the Substance. While no such agreement was ever made available from 2010 to 2018, the Applicant's request was addressed to the First Consortium Manager, and there is no evidence that the Other Party ever became aware of it.

27. As to the negotiations carried out in 2019, it appears from the negotiation between the parties that no agreement was achieved because of the unavailability of a cost breakdown satisfactory to the Applicant. More specifically, the Applicant claimed that the documents provided by the Other Party did not include enough information to understand how the sharing of the costs had been calculated, while a precise figure for the LoA purchase had been provided by the Other Party.

[29] E-mail message of the Applicant of 17 December 2019.
[30] E-mail message of the Applicant of 19 December 2019.
[31] E-mail message of the Other Party of 19 December 2019.
[32] E-mail messages of the Applicant of 20 December 2019, 09:15 and 09:24.
[33] See, to this effect, Decision of the Board of Appeal of 15 April 2019, Case A-010-2017, *REACH & Colours and REACH & Colours Italia*, paragraph 85.
[34] E-mail message of the Applicant of 14 November 2010.

28. As made apparent by the negotiation between the parties, a data sharing agreement was already in place among SIEF participants at the time of the negotiations. Article 2(2) of Implementing Regulation 2016/9 is therefore applicable.

29. This provision requires the Other Party to provide, upon request by the Applicant, the following information:

    - an itemisation of study costs and administrative costs incurred after the date of entry into force of the Implementing Regulation (Article 2(2)(a) of Implementing Regulation 2016/9);

    - proof of the cost of any study, completed before the date of entry into force of the Implementing Regulation (Article 2(2)(b) of Implementing Regulation 2016/9);

    - an itemisation, on a best-effort basis, of all other study costs and administrative costs incurred before the date of entry into force of the Implementing Regulation (Article 2(2)(c) of Implementing Regulation 2016/9).

30. In addition, Article 30(1) of the REACH Regulation requires the Other Party and the Applicant to *'make every effort to ensure that the costs of sharing the information are determined in a […] transparent […] way'*. Article 2(1) of Implementing Regulation 2016/9 requires a data sharing agreement to be clear and comprehensible and to feature, *inter alia*, *'a cost-sharing model'*.

31. A situation where a data sharing agreement has already been reached by previous registrants falls, in principle, under Article 2(2) of the Implementing Regulation and not under Article 2(1). However, the provision of a cost sharing model set forth by Article 2(1) is the expression of a generic obligation of transparency resulting from Article 30(1) of the REACH Regulation. According to this requirement, the parties in a negotiation must exchange information on the identification of the studies to be shared, the cost of those studies and how that cost is divided among multiple entities. Therefore, a previous registrant must necessarily make available, upon a potential registrant's request, clear and comprehensible information on the cost sharing model applicable to the proposed agreement.

32. In the present case, the Other Party requested a precise fee to the Applicant for the purchase of the LoA. This suggests that additional information on the other participants to the agreement was available to the Other Party. However, the cost breakdown provided by the Other Party did not include information on how overall costs would be shared among registrants, nor on how the LoA cost for the Applicant had been calculated.[35] Information on the sharing of costs could be found in the draft data sharing agreement[36] and in the *'cost sharing process document'*[37]. Such information was formulated in general terms and, notably, it did not include details on the number of registrants sharing the data at the time of the negotiations, nor their tonnage band(s) or the existence of possible opt-outs. As it was impossible to link the costs listed in the breakdown and the requested LoA fee, the Applicant was left in the uncertainty on how the cost sharing would operate, in practice, among co-registrants.

33. The Applicant first requested a data sharing agreement on 20 November 2019,[38] i.e. one month before the submission of the application for a permission to refer. Such request was reiterated on 25 November 2019, with express reference to the price and conditions for the

[35] Document [redacted] – *Cost and income reconciliation to 31 May 2018'*.
[36] Document *'Contract : Substance:* [redacted], 20 December 2019.
[37] Document *'Letters of Access from* [redacted]*'*.
[38] E-mail message of the Applicant of 20 November 2019, 16:07.

purchase of a LoA.[39] The further request of the Applicant to the Other Party concerning the LoA price calculation and the sharing of costs among registrants, on 10 December 2019,[40] was prompted by the lack of information provided until then in that respect. Therefore, the overall time allowed before the submission of the application for a permission to refer appears sufficient to address the Applicant's request. This is also in light of the circumstance that, as mentioned, the final LoA cost was readily available to the Other Party, and so should have been the information needed to calculate it.

34. It follows from the considerations above that the Other Party did not provide clear and comprehensible information on the cost sharing model applicable to the proposed data sharing agreement, despite the Applicant's multiple requests in that sense.

35. This breach of the transparency obligation by the Other Party made it impossible for the Applicant to come to an informed decision concerning the proposed LoA purchase, and for both parties to reach a data sharing agreement in a transparent way.

36. This case refers to information requested to the Other Party by the Applicant for a registration in the [redacted] tonnage band.[41] As this decision is adopted under Article 30(3) of the REACH Regulation, its scope must be limited to information involving tests on vertebrate animals.

D. Conclusion

37. The Other Party failed to comply with its obligations to reach an agreement in a transparent way set out in Article 30(1) of the REACH Regulation and Article 2 of the Implementing Regulation.

38. Therefore, ECHA grants the Applicant a permission to refer to the studies specified in Annex II.

[39] E-mail message of the Applicant of 25 November 2019, 12:07.

[40] E-mail message of the Applicant of 10 December 2019.

[41] E-mail messages of the Applicant of 20 November 2019, 16:07, and 25 November 2019, 12:07.