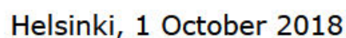
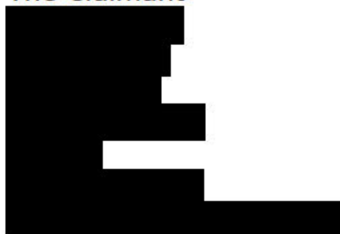


Helsinki, 1 October 2018

The Claimant



Copy to:
The Other Party

Represented by

Decision number:
Dispute reference number:
Name of the substance (the 'Substance'):

EC number of the Substance:

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')[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

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[3].

B. 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.

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. 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[4]

Director of Registration

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.

[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 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.

5. In particular, every effort means explaining the cost sharing model employed in the data sharing agreement, as set out in Article 2 of the Commission Implementing Regulation. The data sharing agreement shall be clear and comprehensible to all parties and shall include, inter alia, the itemisation for all relevant costs and a cost sharing model with a reimbursement mechanism. When the itemisation and justification of data costs are provided, potential registrants are able to assess on an objective basis whether the requested compensation is fair, transparent and non-discriminatory. Any delays need to be justified, and a delay cannot in any case be justified if it results in obstructing potential registrants that have contacted the other company in a timely manner from registering.

B. Summary of facts

6. This summary of facts is based on the documentary evidence submitted by the Claimant on 24 May 2018 and by the Other Party on 8 June 2018.

7. On 20 February 2018, the Claimant contacted the Other Party regarding the registration of the substance, stating that they had pre-registered it and asking for the '*next steps for the registration and how much [does the Claimant] have to pay for the registration?*'.

8. On 22 February 2018, the Other Party confirmed their lead registrant status, provided the substance identity profile (SIP), and asked the Claimant to confirm substance sameness and provide their tonnage band, after which the Other Party would provide the Letter of Access (LoA) cost and substance information exchange forum (SIEF) agreement for signing. The Claimant replied the same day to ask for clarification concerning the substance identity. The Other Party replied the same day to apologise for the mistake in their previous email. They

confirmed their lead registrant status for the correct substance. The Other Party provided the SIP, '*to ensure your substance [complies] with it.*', and asked the Claimant to provide their tonnage band, after which the Other Party would provide the LoA cost and SIEF agreement for signing.

9. On 23 February 2018, the Claimant stated that their '*yearly production is* ▇▇▇ ▇▇▇.', and asked the Other Party to provide the LoA cost.

10. On 9 March 2018, the Claimant sent a reminder.

11. On 27 March 2018, the Other Party stated that they were '*calculating the cost of the LoA and [would] come back to [the Claimant] shortly*'.

12. On 4 April 2018, the Claimant sent a reminder.

13. On 5 April 2018, the Other Party stated that after the parties' '*conversation this morning*', the exact LoA cost was still being calculated and would be sent once ready, but according to an estimation it '*should be around* ▇▇▇ *€.*' They noted that '*[s]uch information is only given as guidance and cannot be considered as the final price*.'

14. On 9 April 2018, the Other Party apologised for the delay and said that their '*finance team [was] finalizing the LoA cost*'.

15. On 11 April 2018, the Other Party informed the Claimant they had sent '*the project manager a reminder*', and promised to keep the Claimant '*informed on further developments*.'

16. On 4 May 2018, the Other Party apologised for the delay, provided an estimated cost of ▇▇▇ euros for the LoA, and stated that the price would '*need to be reviewed after the 2018 deadline*'.

17. On 17 May 2018, the Claimant thanked the Other Party for their answer but expressed concern that the Other Party had misunderstood, as the Claimant was a small enterprise. They questioned the provided estimated cost by stating that it '*indirectly inform[s] [the Claimant] that [the Other Party's] LoA would have costed at least* ▇▇▇ *euros*'. The Claimant doubted that the Other Party could provide invoices worth ▇▇▇ euros or more, and stated that since there were more co-registrants, it meant '*that the real pricing according to your estimations is far more than* ▇▇▇ *euros*'. Furthermore, the Claimant stated that they had asked for '*laboratory pricings*' for comparison, which were '*far less than [the] calculation breakdown [the Other Party] have offered [to the Claimant]*'.

18. The Claimant also asked for a cost breakdown, '*including an explanation of how the overall costs have been calculated*'. They stated the possibility of filing a dispute with ECHA, and asked the Other Party to '*recheck the pricing, [...] breakdown of the pricing according to our production capacities and enterprise size*'. The Other Party replied the same day, on 17 May 2018, saying that they had '*not said that the dossier costed* ▇▇▇', but that the price at that stage was shared between only the lead registrant, one co-registrant, and a potential new LoA buyer. In the same message, the Other Party asked for clarification as to whether the parties were talking about the same substance.

19. On an unclarified date—but which, based on the chronology of the evidence received from both the Claimant and the Other Party, was either 17 or 18 May 2018—the Claimant confirmed the substance name, and stated that the price of the dossier could be '*calculated approximately*', because as the Other Party produced ▇▇▇ tonnes annually '*with a large enterprise category*', the Other Party should '*have [paid]* ▇▇▇ *and more, and*

that's only if [the] companies were involved'. [5]

20. On 18 May 2018, the Other Party provided a cost breakdown for potential registrants in the tonnage band of by annex, with general costs, dossier costs, and SIEF management costs included, and stated their willingness to support the Claimant in the registration process.

21. On 21 May 2018, the Claimant, unsatisfied with what the Other Party had provided, asked for the '*total costs for the dossier*', in the '*spirit of fairness and transparency*', '*before [the Claimant] resort[s] to a data sharing dispute with ECHA*'. They stated that the '*pricing for the annexes for a shareholder of the LoA [was] definitely too high*', and that the pricing was questionable since more toxic substances had '*lesser price*' than this.

22. On 22 May 2018, the Other Party provided a cost breakdown for the dossier as a whole by annex, with general costs, dossier costs, and SIEF management costs included, with a total cost of euros. The same day, the Claimant questioned whether it was fair that they, with a tonnage band of , had to pay a fifth of the costs, and the Other Party, with a tonnage band of and producing more than the Claimant, would pay only five times more for the whole dossier. The Claimant also stated that as the Other Party was a '*category company*' and the Claimant a '*[category]*', the cost should be '*deducted*', as '*this process until now [has been] discriminatory towards* ' The Other Party replied the same day to ask for more time to '*prepare and send [the Claimant] a more detailed description of the costs'*, as the deadline meant they had a '*huge amount of requests*'.

23. On 23 May 2018, the Other Party said that they were preparing the file and would come back to the Claimant shortly.

24. On 24 May 2018, the Claimant informed the Other Party that they would file a dispute with ECHA. The same day, 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.

C. Assessment

25. As explained in section A., ECHA assesses the efforts made by the parties in the negotiations that were outlined in section B. Making every effort means that the existing and potential registrants must negotiate in a clear and constructive manner to enable parties to find a mutual agreement on the sharing of data. Article 30 of REACH, completed by the Implementing Regulation 2016/9, obligates parties to determine costs related to data sharing in a fair, transparent and non-discriminatory manner, and clarifies that each party needs to pay for only the data they need to fulfil the information requirements applicable for their registration.

26. According to Article 2(2) of the Implementing Regulation 2016/9, previous registrants must upon request provide potential registrants with the itemisation of all relevant costs and the proof of such costs without undue delay. Providing this information without undue delay is necessary to establish a solid basis and starting point for the cost sharing discussions between the parties. Via this information, a potential registrant is able to assess the requested costs on an objective basis. No dossier-related cost can be properly understood and, if necessary, challenged, if the above information is not supplied by the existing registrant.

[5] As mentioned, although the email is present in both parties' evidence, there is no date attached to the email. However, in both parties' evidence the email is located in the same order regarding time period, between messages sent on 17 May and 18 May 2018.

27. The Claimant initiated the negotiations with the Other Party by expressing their interest in registering the Substance and asking about the '*next steps*' for registration.[6] On 22 February 2018, the Other Party asked the Claimant about their anticipated tonnage band and for a confirmation of the substance identity, upon which they would provide the LoA cost and the SIEF agreement for the Claimant's signature. However, contrary to that assertion, the Other Party did not revert to the Claimant with the LoA cost and the SIEF agreement. It took until 4 May 2018, and several reminders from the Claimant, before the Other Party provided the Claimant with the LoA cost for their tonnage band, and until 18 May to provide any form of a cost breakdown.

28. ECHA notes that the Claimant could have been more precise and specific in what they required from the Other Party. For instance, after their request on 17 May for a '*breakdown of the pricing*', the Claimant noted on 21 May 2018, having received a cost breakdown by annex, that '*[t]he pricing for the annexes for a shareholder of the LoA is definitely too high, all the prices are very questionable*'. A mere allegation that prices are too high does not help the parties reach a common understanding of how costs are best shared; however, providing a cost breakdown endpoint by endpoint may have helped the negotiations. The Other Party is under the obligation to provide a cost itemisation and a description of the cost sharing mechanism according to Article 2(1) of Implementing Regulation 2016/9. Whether or not the Claimant uses the terminology usually associated with data sharing negotiations, it is part of making every effort for the Other Party to provide such itemisation and a description of the cost sharing mechanism, especially when the potential registrant shows that they do not understand their share of the costs that the existing registrant asks them to pay.

29. In order to make every effort in the negotiations, a claimant must submit their data sharing dispute as a measure of last resort. ECHA notes that the Claimant made requests for an explanation of the costs and the cost sharing mechanism on 17 May 2018. However, when the Claimant submitted the dispute on 24 May, they did not give the Other Party a chance to react to this request. The Claimant could have continued negotiations longer and submitted the dispute at a later date. ECHA recognises the possibility that another week of negotiations could have led to an agreement between the parties.

30. However, the lack of time at the end of the negotiations is wholly attributable to the Other Party. It was apparent to the Other Party that the Claimant was under a regulatory obligation to register by the end of May, when the registration deadline of Article 23(1) of REACH expired, and that they needed access to the data and the joint submission before then. The Claimant initiated the negotiations three months in advance, which would normally leave enough time to find an agreement.

31. According to Article 2(1) of Implementing Regulation 2016/9, a data sharing agreement—including amongst others an itemisation of the data, the cost and the cost sharing model—must be provided without undue delay. Article 30(1) of REACH obliges an existing registrant to provide such information at the latest after one month. To make every effort, the Other Party should have taken the registration deadline into account and lived up to their obligation to provide the data sharing agreement according to Article 2(1) of Regulation 2016/9 without undue delay. By taking over two months to provide the cost of the LoA for their tonnage band to the Claimant, the Other Party did not make every effort to find an agreement.

D. Conclusion

32. Based on the above, ECHA concludes that the Claimant made efforts to find an agreement.

33. By not addressing the Claimant's requests in a timely manner, the Other Party did not make

[6] Claimant; 20 February 2018.

every effort to reach an agreement with the Claimant in a fair, transparent and non-discriminatory way, as required by the Implementing Regulation 2016/9.

34. 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.”