[redacted]

Helsinki, 18 September 2018

The Claimant

[redacted]

Represented by

[redacted]

Copy to:
The Other Party

[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 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 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. 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

[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.

[redacted]

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.

4. In particular, every effort means providing clear and comprehensible information regarding different cost items, such as study costs and administrative costs, as set out in Article 2(1) of the Implementing Regulation 2016/9.

5. Article 30(1) of the REACH Regulation obligates existing and potential registrants to make every effort to reach an agreement on the sharing of information. Furthermore, Article 30 of REACH as further detailed 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 only needs to pay for the data they need to fulfil the information requirements applicable for their registration. Moreover, the Implementing Regulation 2016/9 provides minimum requirements for the parties to discuss during their negotiations, such as the cost sharing principles, covering also potential additional future costs, and a reimbursement scheme when new registrants join the registration. It also requires the existing registrants to provide upon request an itemisation of data and administrative costs including justifications of all cost items.

[redacted]

B. Summary of facts

6. This summary of facts is based on the documentary evidence submitted by the Claimant on 26 May 2018 and by the Other Party on 11 June 2018.

7. On 4 October 2016, the negotiations started. The Claimant requested from the Other Party the cost of the letter of access (LoA) for the substance for tonnage bands [redacted] and [redacted].[5] Subsequently, the parties exchanged several emails in rapid succession, where the Claimant detailed their request on the cost breakdown of the data, and the Other Party gradually detailed that information. On 6 October 2016, upon the request of the Claimant, the Other Party provided an indication of costs differentiated by study costs and administrative costs over the whole registration. They also mentioned that a reimbursement was foreseen after the 31 May 2018 deadline when the number of registrants would be known.[6]

8. On 11 October 2016, the Other Party provided the Claimant with a document called '[redacted] including the columns '[redacted]', '[redacted]', '[redacted]', '[redacted]', '[redacted]', and '[redacted]'. They explained that as study values they have used '*invoices,* [redacted] *prices [of] 2007 (+*[redacted]*% inflation)*', and added administrative costs '*based on CEFIC*'. The Other Party mentioned that [redacted] studies and some [redacted] studies had to be performed on [redacted] due to the nature of the substance, and that the costs for [redacted] and [redacted] studies were divided by the number of registrations they would be used for. Finally, the Other Party noted that the prices of two testing proposals were not yet included in the [redacted] LoA price.[7]

9. On 18 October 2016, the Claimant, represented by a consultant, asked five questions on the permissions and necessity of the tests planned or conducted. They were concerned about excessive animal testing and mentioned that they could consider opting out from certain endpoints because of this, as they planned to use the substance in [redacted].[8] On 17 November 2016, the Other Party replied by explaining their approach to data collection for the substance. Specifically, they noted that with their approach of using read-across fewer animal tests would need to be conducted.[9] On 18 November 2016, the Claimant acknowledged that there were apparently good reasons to conduct the animal tests as they had been conducted. They nevertheless sought further clarification on the testing costs of different read-across substances, and how they related to the LoA cost for the substance in question as they considered the LoA cost high.[10] The Other Party did not address the question related to dividing costs of the studies that were used also for other substances. This phase of negotiation ended by the Other Party providing the substance identification profile (SIP) of their registration to the Claimant.[11]

10. On 24 August 2017, the Claimant, now represented by another consultant, approached again the Other Party. In their e-mail, they noted that they were '*alarmed by the extremely high proposed LOA charges*'. They also stated that they were '*dissatisfied with the approach which has been taken to the generation of the lead dossier, and the allocation of costs*', and made six generic remarks on these.[12] During the same day, the parties clarified the role of the new consultant as well as the previous exchange between the parties. The Claimant's

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[5] Claimant; 4 October 2016.
[6] Other Party; 6 October 2016.
[7] Other Party; 11 October 2016.
[8] Claimant; 18 October 2016.
[9] Other Party; 17 November 2016.
[10] Claimant; 18 November 2016.
[11] Other Party; 13 February 2017.
[12] Claimant; 24 August 2017, first email.

representative assured that they were '*very well aware of all the various streams of dialogue which have taken place with* [the Other Party] *in the past, with respect to this substance and* [the Claimant].[13]

11. On 31 August 2017, the Other Party promised to work on the Claimant's comments, but mentioned that due to the holiday period this might take some extra time.[14]

12. On 20 October 2017, the Claimant contacted the Other Party as they had not heard back from them. They mentioned that they would order '*own* [redacted] *tests this coming week, if* [they] *don't hear from* [the Other Party] *in the next few days.*' Subsequently, the Claimant would start negotiations with the Other Party to procure the necessary [redacted] tests from the Other Party. Therefore, the Claimant urged the Other Party to send '*a very good LOA offer as soon as possible*'.[15]

13. On 26 October 2017, the Other Party replied to the Claimant and explained their data selection strategy at some length. They noted, *inter alia*, that avoiding animal testing was their guiding principle and therefore read-across was used rather than conducting new tests. As a result, sometimes more than one study was needed per endpoint. However, if these tests were used for more than one substance, the price of the study was split accordingly (e.g. if a study was used for two substances, the cost of the study was split 50/50 between the two registrations). The Other Party further explained certain specificities in their testing approach for different endpoints, stemming from the nature of the substance ([redacted], [redacted] in the SIP of the registration).[16]

14. The Other Party concluded their message by stating that '*if* [the Claimant is] *going to run separate* [redacted] *tests and* [is] *asking to buy additional* [redacted] *studies from* [the Other Party] *for an opt-out dossier,* [they] *as well will have the need to demonstrate the* [redacted] *of the target material for which* [the Other Party] *used the read-across approach*'.[17]

15. On 30 October 2017, the Claimant confirmed that they would not buy a full LoA from the Other Party, but do a partial opt-out instead, since '[the Claimant is] *indeed running a number of [their] own* [redacted] *tests and are now asking access to a few studies from* [the Other Party]'[18]. The Claimant wanted to purchase three specific [redacted] studies ([redacted]; [redacted] and [redacted]; [redacted]). They asked for the price of these studies, and a breakdown between technical and administrative costs.

16. On 19 December 2017, after a reminder form the Claimant, the Other Party replied. They explained that they '*are struggling with the question whether* [the Claimant] *fit*[s] *in* [the Other Party's] *registration or not.*' Therefore they asked for the Claimant's SIP, and asked them to confirm that they want to register under the same EC number as the Other Party. Finally, they asked the Claimant to '*indicate which studies (related to which test substance)* [the Claimant] *want to use for* [their] *registration as read across*'.[19]

17. On 11 March 2018, the Claimant contacted the Other Party and confirmed that they would only wish to buy access to specific studies. The Claimant had revised their needs and now requested the price for [redacted] specific studies ([redacted]; [redacted]; [redacted]; [redacted]; [redacted]

[13] The Claimant; 24 August 2017, second email.
[14] The Other Party; 31 August 2017.
[15] The Claimant; 20 October 2017.
[16] The Other Party; 26 October 2017.
[17] The Other Party; 26 October 2017.
[18] The Claimant; 30 October 2017.
[19] The Other Party; 19 December 2017.

[redacted]

[redacted]; [redacted]).[20] On 20 March 2018, the Other Party replied that their legal department was seeking clarifications on the procedure through which the Claimant would register the substance by partially opting out.[21]

18. On 28 March 2018, the Other Party asked the Claimant to provide a list of studies in possession of the Claimant, per endpoint. The Other Party stated that '[a]*fter that* [the Other Party] *can give* [the Claimant] *the price to join* [their] *submission*'[22]. The Other Party explained that '[i]*n this case the studies of the endpoints where you do not have any own studies will be part of the cost compensation. You do not need to buy any studies as you are joining for those studies into our submission.*'[23]

19. On 8 April 2018, the Claimant sent an email where they noted that before continuing discussion on the access to all studies, they want to clarify the situation concerning three studies that have been used for registration of another substance also ([redacted]; [redacted]; [redacted]). They noted that for this other substance, the Other Party had asked [redacted] € as study access costs for the three studies, while the Claimant had demonstrated that rather [redacted] € would be a fair and reasonable price. Therefore, they offered to pay [redacted] € for the REACH only access to the three studies for both substances.[24]

20. On 9 April 2018, the Other Party explained in an email that '[a]*s* [they] *understood,* [the Claimant] *will go for a joint submission for this EC number, but with partial opt-out as explained*'. Therefore, in their cost overview, the Other Party provided the price for the joint submission at [redacted] '*excluding the studies/endpoints where* [the Claimant] *ha*[s] *own studies* [which] *is reduced to* [redacted] €'. For the Claimant's partial opt-out where they would request access to the six studies (see paragraph 17), the Other Party did not provide any price. However, the Other Party insisted instead that for the joint submission, excluding the other studies that the Claimant might have, the price would be [redacted] €. The Other Party mentioned that '[w]*here studies are used in other registrations* [the Other Party] *have already divided the costs by the number of registrations.*'[25]

21. On 14 April 2018, the Claimant stated that they '*remain confused as to how* [the Other Party] *have calculated* [their] *proposed data-access costs for the related substances'*. They added that '*these prices are excessive, given the few studies* [the Claimant] *is interested in'*. The Claimant asked the Other Party to provide more transparency and details on the costs assigned to each study, as they considered the data access costs excessive. They noted that the following factors should be considered: number of registrants for each substance, use of data across [redacted] substances and REACH-only use. They also provided a template to this end, which they asked the Other Party to fill in. The template included data fields splitting the study and administrative cost per endpoint for each of the [redacted] substances, and a column for comment on how the costs were calculated.[26]

22. On 29 April 2018, as they had not heard from the Other Party despite one reminder, the Claimant provided their own template filled with their own cost proposal, and offered to buy five studies ([redacted]; [redacted]; [redacted] and [redacted]; [redacted]; [redacted]), including the three studies needed for the registrations of [redacted] substances ([redacted]; [redacted]; [redacted]) for [redacted] €. This offer was made '*for the purposes of REACH*

[20] Claimant; 11 March 2018.
[21] Other Party; 20 March 2018.
[22] Other Party; 28 March 2018.
[23] Other Party; 28 March 2018.
[24] Claimant; 8 April 2018.
[25] Other Party; 9 April 2018.
[26] Claimant; 14 April 2018.

[redacted]

registration of both [the substance] & [another substance]'.[27]

23. On 4 May 2018, the Other Party replied that the joint submission price of [redacted] €, offered on 9 April, still held. This price did not include the '*the studies* [the Claimant has] *on* [their] *own (where* [the Claimant] *are doing a partial opt-out)*' and that the study prices have already been divided by the number of registrations the study is used in. The Other Party also reminded that there would be reimbursements after May 2018 when the number of co-registrants is known.[28]

24. On the same day, the Claimant replied and expressed their confusion about the LoA costs proposed by the Other Party for [redacted] substances. The Claimant asked the Other Party to confirm whether the Claimant's understanding of those costs was correct.[29] The Claimant reiterated their request for the Other Party to provide more transparency on their cost calculation, e.g. by filling the template provided by the Claimant, in order to justify the LoA cost.[30] To support the prices used in their offer, the Claimant provided a price list from a [redacted] laboratory.[31] Finally, the Claimant stressed the urgency of their requests due to the closeness of the 31 May 2018 REACH registration deadline, and they evoked the possibility of lodging a data sharing dispute with ECHA. However, they mentioned that they would like to avoid that path if possible.[32]

25. On 15 May 2018, the Other Party replied and explained that there were more than five studies needed to cover the endpoints for which the Claimant did not have data. A read-across approach had been used to avoid animal testing and hence, more than one study had been used per endpoint. The Other Party referred to the study list that had been sent to the Claimant early in the negotiations. The Other Party reiterated that the studies already owned by the Claimant had been removed from the cost calculation, and that if studies had been used for more than one registration, the cost had been divided accordingly. The Other Party concluded that '[t]*he LoA cost for a joint submission related to the SIEF agreement of* [the substance] *for* [redacted] *excluding the studies* [the Claimant has] *by* [their] *own but including all further studies and admin costs (already provided) of* [the Other Party] *are* [redacted] *€.*' The Other Party also mentioned that a cost sheet had been provided to the Claimant '*in the beginning of* [their] *discussion*'.[33]

26. On 17 May 2018, the Claimant communicated that they would buy three studies necessary to complete the registration of one of the substances for [redacted] € ([redacted] and [redacted]; [redacted]; [redacted]).[34]

27. On 26 May 2018, the Claimant returned to the Other Party stating that they did not accept the LoA price offered by the Other Party for the remaining substance to register. The Claimant considered that the price request was excessive, taking into account that three out of five studies were used in the registration of another substance. The Claimant pointed out that they had earlier agreed to purchase, and had subsequently paid for, three studies, but still considered '[the Other Party's] *LOA price to be unjustified and unfair*'.[35] Therefore, the Claimant considered that they had '*demonstrated significant flexibility and a willingness to compromise*' throughout the negotiations.[36] The Claimant also noted the efforts they had

[27] Claimant; 29 April 2018.
[28] Other Party, 4 May 2018.
[29] Claimant; 4 May 2018.
[30] Claimant; 4 May 2018.
[31] Claimant; 4 May 2018.
[32] Claimant; 4 May 2018.
[33] Other Party; 15 May 2018.
[34] Claimant; 17 May 2018.
[35] Claimant; 26 May 2018.
[36] Claimant; 26 May 2018.

made in the negotiations and observed that the Other Party had failed to provide the transparency for the data costs which the Claimant had repeatedly asked for.[37]

28. On 26 May 2018, 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. Regarding data, they requested access to five specific studies.

C. Assessment

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

30. In the case at hand, ECHA notes that both parties made efforts in the early phase of the negotiations. Both parties responded promptly to each other's emails. The Claimant gradually detailed the information they requested on the cost breakdown of the data, and the Other Party responded by providing more details. In the end, the Other Party provided, for each study used in their registration, the price and a reference to the cost basis.

31. However, at a later stage of the negotiations, when the Claimant wanted to opt out and sought access to specified studies only, the Other Party did not provide an itemisation of the administrative costs for those studies. The Other Party provided the cost breakdown only in a summary form, indicating the split between study costs and administrative costs for the whole registration, and by referring superficially to Cefic as the basis for administrative costs. The administrative costs of the studies requested by the Claimant constituted a significant part of the total study costs and therefore, by not providing an itemisation of these costs, the Other Party failed to make every effort to reach a data-sharing agreement in accordance with Article 2 of the Implementing Regulation 2016/9.

32. ECHA notes that the Other Party did not provide this itemisation of costs, but indicated a lump sum for joining the joint submission, while the Claimant made clear they were only requesting access to specific studies. By doing this, the Other Party prevented the Claimant from fully understanding the costs included in the price the Other Party was asking for. Given this lack of information, the Claimant was not able to assess in an objective manner whether they were requested to pay only for studies and administrative costs of those studies that they had requested the Other Party to share.

33. Furthermore, when the Claimant came back to specify the studies they were interested in, the Other Party ceased to make efforts to come to a mutually acceptable conclusion. The Other Party no longer provided explanations to the Claimant to allow them to understand the Other Party's calculation method and the costs of the studies. The Claimant, on the other hand, made efforts by detailing which information they sought for the studies, preparing a template where the Other Party could provide this information, later justifying their own counter-offer in this template, and by providing a price quotation of a [redacted] laboratory to support the prices in their offer. The Other Party reacted to these efforts by merely insisting on the price they had indicated earlier, without explaining any further their position, hence preventing the negotiations with the Claimant from moving forward.

D. Conclusion

34. The Claimant made every effort to reach an agreement on access to the joint submission and the sharing of information by making clear requests and by providing explanations for their claims, whereas the Other Party did not provide the requested detailed cost breakdown and justifications that would have allowed the Claimant to understand the LoA cost.

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[37] Claimant; 26 May 2018.

[redacted]

35. Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to the studies requested from the Other Party involving tests on vertebrate animals, as specified in Annex II.