[redacted]

Helsinki, 21 November 2018

The Claimant

[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 finds that you made every effort to find an agreement on data sharing and grants you permission to refer to the studies involving testing on vertebrate animals you requested from the Other Party and access to the joint submission.

ECHA makes a copy of the respective robust study summaries available to you and the permission to refer to the studies takes effect once they are submitted. Once all studies involving testing on vertebrate animals that you requested from the Other Party have been submitted, ECHA will give you a reasonable time to complete your registration and technical instructions on how to prepare your dossier.

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,

[redacted]

The reasons for this decision are set out in Annex I. The list of endpoints, for which the negotiated studies have already been submitted are listed in Annex III. Instructions on how to submit your registration dossier will be provided to you with a separate communication later when the rest of the studies have been submitted or upon request.

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

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.

C. 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.

Yours sincerely,

Christel Schilliger-Musset[4]

Director of Registration

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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.

[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. In addition, Article 30(2) of the REACH Regulation establishes that, if a relevant study is not available within the SIEF, and no agreement is reached as to whom should conduct it, ECHA shall specify which registrant shall perform the test.

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 the 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 that, pursuant to Article 2 of the Implementing Regulation 2016/9, an existing registrant is obliged to provide a potential registrant, upon their request, an itemisation of the data and costs to be shared. This entails an itemisation and justification of all costs, including cost per each study, and administrative costs, and providing proof of cost of studies completed before the entry into fore of the Implementing Regulation 2016/9. Part of making every effort and being transparent pursuant to Article 2 of the Implementing Regulation 2016/9 is to justify and explain the cost of each study to enable the potential registrant to evaluate, whether the proposed cost is justified or not, and how it fulfils the information requirements laid down in the REACH Regulation. A clear and transparent breakdown allows the potential registrant to understand, what the cost of the LoA comprises, hence being a prerequisite for successful data sharing negotiations.

[redacted]

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 28 May 2018 and by the Other Party on 14 June 2018. The negotiations took place between a potential registrant, the group of companies it is party to and its consultant (hereinafter referred individually and collectively as the 'Claimant'), on the one side, and the Other Party, on the other.

6. On 4 January 2017, the Other Party inquired whether the Claimant was interested to register and had any data for the Substance and another substance. On 6 January 2017, the Claimant replied that they were '*interested in the [Substance] registration, with [the Other Party] as Lead registrant*', and asked for a LoA for [redacted]tpa. On the same day, the Other Party explained that they planned to register the Substance for [redacted]tpa by March 2018, and that final costs would be available later as '*new studies are running until January 2018'.* Tonnage band upgrade would be possible but would require additional data. The Other Party '*[was preparing] for additional studies of [the Substance and another substance] in 2018, considering the results of the studies for Annex*[redacted]'. They provided estimated costs for [redacted] tpa tonnage bands, which '*are to be equally shared between the SIEF members*', the Claimant being the only interested co-registrant.

7. On 4 July 2017, the Claimant asked the Other Party to '*detail the costs for the Registration dossiers* [redacted] *tpa and explain the cost evaluation method*'. The Other Party replied on 12 July 2017, indicating that the '*cost estimation is based on [their] experience*' and follows '*the recognised research paper of Manfred Fleischer*', mentioning that '*there are also other data-sharing contracts possible, but this is according to [their] understanding the obligation under REACH*'. On 17 July 2017, the Claimant replied that they '*better understand the range of costs [was] based on this article and not on the reality of the substance*' and expressed their interest to be closely involved in the '*elaboration of the registration dossier*' for the [redacted]tpa, for a '*critical rereading of the datagap'*. The Claimant asked the Other Party to '*propose […a] way to proceed (specific contract, organisation,…)*'.

8. On 21 July 2017, the Other Party explained that they would prepare the Annex [redacted]dataset by May 2018 and '*may hand over the lead registrant role to another SIEF members for higher tonnage bands*', '*[a]fter dossier submission, and data-sharing compensation payment*'.

9. On 25 July 2017, the Claimant rejected the idea of changing the lead registrant (LR) later as '*absolutely non-constructive*', stating that '*datagap is a global approach and it is unscientific to separate the two annexes* [redacted]'. The Claimant noted that, as LR, the Other Party must submit the joint registration '*for the […] most stringent deadline for registration of SIEF members (i.e.* [redacted]*)*', and that because the Other Party had [redacted], the Claimant '*[would need] to participate actively in the construction of the registration dossier*'. The Claimant thus proposed three options: (i) The Other Party would be the LR and share the Annex [redacted] datagaps with the Claimant, who would be actively involved. The Other Party would take care of testing for [redacted] tpa; (ii) The Other Party would be the LR and would take care of Annex [redacted] and the Claimant would determine Annex [redacted] datagaps together with the Other Party and take care of testing for Annex [redacted]. For this option, a '*special contract [would need] to be established between the parties'*; (iii) The Claimant would become the LR for the whole dossier.

10. On 26 July 2017, the Other Party replied that the '*best way forward would be if [the Other Party] would agree to prepare the* [redacted]*tpa dossier by May 2018'*, subject to '*internal approval';* otherwise, they would '*come back on [the Claimant's] options*'. They noted that '*it is possible to submit a dossier with a note that studies are under preparation'* since finishing all additional studies by May 2018 '*may be unrealistic'*. The Other Party asked whether the Claimant was interested only in data sharing for REACH purposes, or whether they had a '*general data sharing interest*'.

11. The Claimant wrote on 28 July that they wanted to become a '*data owner of the new generate[d] data for a general interest*'. The Other Party confirmed on 1 August 2017 that they would '*prepare the* [redacted] *tpa REACH dossier […] by May 2018*' and would '*draft a data sharing agreement […] taking into account [the Claimant's] interest of equal rights of use*'.

12. On 28 August 2017, the Claimant asked after the data sharing agreement and repeated their '*wish to actively participate to the construction of the Registration dossier (reading of datagap report for* [redacted] *tonnage band)*'. They sent a reminder on 14 September 2017. On 28 September 2017, the Other Party sent a draft SIEF agreement, writing that cost calculation would take into consideration the parties' tonnage bands and data needs. The SIEF agreement was addressed to a '*Non-Lead Member*' (a registrant '*that agrees to rely on the Joint Registration Dossier prepared and/or made available by the Lead Registrant*'). The agreement defined also '*Lead Registrant*' and separately '*Lead Member […] who participates to the SIEF discussions in order to compile the Joint Registration Dossier*'.

13. On 2 October 2017, the Claimant wrote they wanted to be a '*LEAD-MEMBER in a way to actively participate to the registration dossier elaboration in term of: [i] datagap validation, [ii] Integrated Testing Strategy Validation, and [iii] cost validation*', and to become a '*data owner of the new generate[d] data for a general interest*'. To this end, they asked to receive a '*rectified agreement*' and '*the datagap of the substance*', as time was becoming of the essence.

14. On 12 October 2017, the Other Party sent '*an overview of [their] data gap analysis [and] REACH strategy*', explaining they would prepare a dataset '*for [the Substance] and [another substance] allowing read across of data*'. They explained that all study reports for the Substance would be finalised '*until January 2018*' and for the other substance '*until April 2018*'.

15. On 13 October 2017, the Claimant (in the person of the consultant) observed that '*annex* [redacted] *is entirely completed by read across on [another substance]*', and that they have explained to the Claimant (the potential registrant) that their interest to own data was not '*consistent for [A]nnex* [redacted] *studies as there [was] only read-across strategy*'. The Claimant wrote that the registration still '*remain[s] very important*' for them and asked the Other Party to keep them informed about the progress with the dossier.

16. On 8 February 2018, the Claimant contacted the Other Party to enquire whether there were '*any documents ready for review*'. The same day, the Other Party explained that the finalisation of the studies was delayed but '*if required by [the Claimant], [the Other Party could] make available a* [redacted] *Dossier […] in time*'. However, if a tonnage band [redacted] would be '*sufficient*' '*until August*', the Other Party would '*prefer to prepare an* [redacted] *update in the second half of the year*'. The Other Party proposed to prepare the dossier and the data sharing agreement for the Claimant to review '*until the end of March*'. The Claimant could then check the dossier in April, and the Other Party could finalise the dossier in May.

17. On 9 February 2018, the Claimant replied that they need the [redacted] dossier before 1 June 2018 and stated that the Other Party was qualified for the '*ISSUE 10 […] cited in the DCG3 support ECHA document*'. The Claimant asked to receive the dossier and SIEF agreement '*during [M]arch*', to which the Other Party replied, on 20 February, that they would '*follow up*' in March on the data sharing agreement, and share the dossier in April.

18. On 3 April 2018, the Other Party promised to share a draft data sharing agreement '*asap*' and proposed a call to '*explain [their] calculations*', to which the Claimant agreed, asking on 4 and on 9 April 2018 to receive '*an overview of the costs entries*' before the call.

19. On 9 April 2018, the parties had the call and the same day Claimant sent '*key points*' of the

[redacted]

call for comments to the Other Party. The Claimant wrote that the Other Party's strategy was to submit [redacted]tpa dossier with temporary *'QSAR waving'*, but proposed again the DCG solution 10.3 instead. In addition, the Claimant wrote that *'since August 2017'* they had been seeking *'an active role in the preparation of the dossier'*, and had consistently said that they need to register for [redacted]tpa by 31 May 2018, which the Other Party *'agreed with'*. In order to understand the *expensive cost'*, the Claimant asked the Other Party to send *'by the end of the week (w15)'* the *'[c]osts and content of the dossier which will be submitted by May 2018 (including admin and preparation costs)'* and the same *'for a complete dossier* [redacted]*'*, presenting the cost with REACH-only access rights, on the one hand, and *'a full access agreement for [the Claimant] (i.e. for other regulatory purpose]'* on the other hand, including *'refunding calculations and rules'*. On week 16, the Claimant would make their decision, and then *'IUCLID 6 [would] be available by the end of April […] after SIEF agreement signature'*.

20. On 11 April 2018, the Other Party clarified that they would prepare *'a complete IUCLID dossier* [redacted]*'* for the May 2018 deadline and that *'[a]ll tests were ordered last year but some tests will not be finished before the May deadline'*. The Other Party noted that they had decided to submit a DCG 10.3 application.

21. On 13 April 2018, the Other Party sent a cost breakdown for [redacted] indicating cost per endpoint, how each endpoint was filled (i.e. study report, waiver/expert statement or read-across from another substance) and information on study guidelines. The costs [redacted] were based on Fleischer list prices, adding [redacted]% for adjustment because *'the list is from 2007'*. [redacted] endpoints in [redacted] were filled with study reports and their cost based on *'existing invoice'* or *'expected price'* in case the study was ongoing. [redacted] endpoints were filled with waivers or read-across studies conducted on another substance, and the costs were based on invoice of completed or ongoing studies. The table indicated full study costs for all studies and a 'REACH-only' discount. The Other Party noted that the cost for ongoing studies *'may be subject to corrections'*, administrative costs would be added later, *'most likely in a form of a lump sum'*, and that they *'expect[ed] all* [redacted] *studies to be completed'* by the end of April. On 16 April 2018, the Claimant replied that they would comment on the breakdown shortly.

22. Also on 16 April 2018, the Other Party commented on the teleconference minutes the Claimant had shared on 9 April, repeating what they wrote on 11 and 13 April. In addition, regarding the Claimant's wish to be actively involved in the dossier development, the Other Party wrote that *'[a]s a matter of fact [the Other Party] is the lead registrant […and] [t]here is neither a consortium or a cooperation agreement in place'*. Regarding data co-ownership, the Other Party replied that *'[o]nly [the Other Party] is or will be the owner of the studies'*. The Claimant could either get right to refer for REACH registration purposes, in which case they would pay [redacted]% of the full cost of the studies divided by the number of registrants, or *'the access rights for global registration purposes'*, in which case the Claimant would pay the full study costs divided by the number of registrants.

23. Furthermore, the Other Party explained that, in case another co-registrant would join, *'the cost [would] be shared equally between all'* but that the read-across substance *'is a different SIEF […and therefore] the cost calculation is completely separate'* for the studies where read-across was used. If the Claimant would get access to the data for REACH registration purposes only, and if the Claimant *'would decide in the future to register the [read-across substance] as well, […the Claimant would] have to pay again for all the studies'*. If the Claimant would get access for global registration purposes, the paid studies *'[would] be taken into account'* if they would decide to register the read-across substance as well. On the schedule laid down by the Claimant, the Other Party commented that they had already provided the requested list of studies *'already used or [that] will be used for the creation of the dossier'*. The Other Party also stated that the Claimant could get the IUCLID file only after signing the agreement and paying the LoA cost.

24. On 25 April 2018, the Claimant accused the Other Party of taking '*advantage [of] [their] Lead position to preclude [the Claimant] to have access to the discussion on the datagap or to be a co-owner of the studies*'. Moreover, they wrote that the '*LoA is not compliant with the regulation 2016/9*', and that the Other Party '*make[s] [the Claimant] pay a part of [the Other Party's] REACH registration dossier*' for the other substance used for read-across. The Claimant acknowledged that the Other Party was the LR and that there was no cooperation agreement or consortium, but stated that '*the LR role is to organize the SIEF and if a SIEF member wants to be a Lead Member, [the Other Party] has an obligation to exchange with this Lead member to implement an agreement*'. The Claimant pointed out that they had proposed to '*become a Leading member*' during the negotiations.

25. Concerning the testing costs, the Claimant asked the Other Party to propose a '*new version taking into account the regulation 2016/9*', specifying that *'the price must be fair, transparent and no-discriminatory [including information on the] year of the study, Klimishc cotation[sic], read-across'* and justification for potential cost reductions. In particular, the Claimant stated that using the '*Fleischer list with an adjustment (+[redacted]%) to justify a price without detailing the dossier content […] is not transparent*' and that *'the year and the Klimisch cotation of their study'* has to *'be taken into account for price reduction'*. Second, the Claimant stated that *'in the context of read-across approach the study is less reliable (Klimisch 2) than direct application and thus justifies a lower price'* and that paying [redacted]% of the cost for read-across studies was *'not fair especially considering that […] [the Claimant] would not be even co-owner'.* The Claimant asked the Other Party to '*provide a new LoA with the option to be a real co-owner of the studies*' before 4 May 2018. The Claimant noted that '*if a new document is not returned or if the conditions are not acceptable, due the time before the deadline, [they would] submit a dispute to ECHA*'.

26. On 26 April 2018, the Other Party proposed a teleconference. The same day the Claimant (i.e. the potential registrant) replied that they were not available on the proposed times and asked what the purpose of the phone call was as the Other Party already had a '*meeting with [the consultant of the potential registrant]*'. The Claimant reiterated the request of a new LoA with the option to be a real co-owner of the studies before 4 May 2018.

27. On 27 April 2018, the Other Party sent an updated cost breakdown, including also administrative costs and a [redacted]% surplus covering the yet unknown costs related to ongoing work. In addition, they sent LoA costs for the two options, namely the right to refer to the studies for REACH registration purposes only, or the right to use the studies for global regulation purposes, including read-across and sub-licensing right to other SIEFs. The Other Party noted that this was '*somehow equivalent to a co-ownership*', although selling of the studies to third parties was '*restricted to the data owner [the Other Party]*'. The Other Party '*expect[ed] to submit the dossier […] for the tonnage band* [redacted] *in the middle of May 2018*' and asked the Claimant to inform them by 4 May 2018 which of the options they would choose. The Other Party also asked for certain administrative information on the potential registrant and explained the process of receiving the co-registration and data.

28. On 3 May 2018, the Claimant referred to the Implementing Regulation 2016/9 and ECHA's Guidance on data-sharing, noting that '*what is important is that "costs are transparently recorded and their sources clear to the co-registrants"*'. Concerning the use of the Fleischer list as the cost reference for some [redacted] studies, the Claimant noted again that they did not know the study year or the Klimisch cotation, and asked how the costs were justified and if they were based on the *'time [the Other Party] spent on this data by endpoint'.* The Claimant furthermore stated that they '*[could not] consider that the Fleischer list is "proof of costs"*'.

29. Regarding the study reports on Annex [redacted] endpoints, the Claimant noted that the Other Party did not provide '*any detail*' of the studies and that '*consequently, it is not possible to understand the scientific quality and the correcting factors considered by* [the Other Party]' in the cost. The Claimant asked the Other Party to

provide '*value elements for each data*', such as the year of study, Klimisch score, testing laboratory quotations and information on '*the price reduction*'. The Claimant, referring the mentioned Guidance, stated that they could not agree with the proposed cost sharing model due to the '*lack of transparent valuation elements, which is a "critical component in the data-sharing process*"'.

30. Regarding the use of read-across studies, the Claimant asked for detailed costs of tests conducted on the other substance, the year and Klimisch score, testing laboratory quotations, data owner, and cost reduction applied when using the study for the dossier of the Substance. The Claimant repeated that a read-across study is less reliable and stated that ECHA's Guidance on data-sharing '*stress[es] that "factors decreasing the study value may include [...] use in case of read-across, where the substance is not the tested substance*"'. The Claimant argued that '*the contribution of the SIEF of the target substance […] must be lower compared to the SIEF of the source substance*', stating that the proposed cost-sharing model was not fair, in particular because the Other Party was the LR for both substances. The Claimant added that, in similar cases, '*the usual proposal is to pay* [redacted]*% of total cost'.*

31. The Claimant repeated that they had asked to have a '*leading role*' in the preparation of the dossier '*since August 2017*' but the Other Party '*did not provide a [SIEF] agreement including this option'*. The Claimant asked to receive a LoA before 9 May 2018 for [redacted] tpa with '*an acceptable cost'* and with '*the option to be a real co-owner of the studies*'.

32. On 9 May 2018, the Other Party explained that the Fleischer list or similar '*had been used for many years'* by many registrants, and is mentioned in the Director's Contact Group publication DCG3/AP3a on fair, transparent and non-discriminatory cost sharing. Regarding the requested details of study reports, the Other Party highlighted their expertise and know-how, and explained that their policy is that the '*replacement cost or the actual cost proved by invoice has to be shared by all co-registrants for each endpoint*' according to the tonnage band. The Other Party mentioned that '*a Klimisch ranking is not for[e]seen*', noting that '*either an endpoint can be covered by a study or not*' and '*if not [then] further testing is a consequence*'. They pointed out that they had offered a discount for REACH-only purposes on 27 April 2018. Regarding the cost and details of read-across studies, the Other Party wrote that they '*have to explicitly distinguish between the two substances […which] belong to different SIEFs'* and that '*cost sharing between two different SIEFs is not provided for under REACH regulation*'. Regarding the Claimant's requests for transparency and sources of costs, the Other Party responded that they had already provided '*a detailed list of the used studies and administrative costs accrued*' on 27 April 2018, and would reimburse excessive payment once the costs would be fixed.

33. The Other Party moreover added that the parties had '*never signed an agreement which defined a mutual co-operation for the REACH registration*' and that '*a leading role can only have the lead registrant who is responsible for submitting the REACH dossier*'. The Other Party stated that to '*change the conditions [of co-registration] only for [the Claimant] would be unfair to all already existing REACH co-registrants of the substances where [the Other Party] is lead registrant'*. The Other Party invited the Claimant to join the registration under the conditions written in the email of 27 April 2018.

34. On 11 May 2018, the Claimant stated that '[*the Other Party was] not replying to [their] request and [was] not open to find an agreement'* and that the Claimant would submit a dispute to ECHA. The Other Party replied on 14 May that they were open for discussion.

35. On 24 May 2018, the Other Party informed the SIEF that they had '*successfully submitted* a *joint submission dossier*' for [redacted] tpa. The next day, the Claimant requested a LoA for tonnage band [redacted] tpa, '*with details of costs and with the answers to issues already asked*'. In reply, the Other Party stated, on 28 May 2018, that they had already provided the '*details of the co-registration*' and asked which of the options, i.e. REACH-only or global

[redacted]

right to refer, the Claimant preferred.

36. After the last email from the Other Party, on 28 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.

C. Assessment

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

On the cost-sharing model

38. As is apparent from paragraphs 25 and following, above, that during the negotiations the Claimant requested more information and explanations on studies and costs, challenging the Other Party's cost calculation and cost sharing model, in particular after receiving the first cost breakdown in April 2018.[5] The Other Party made some negotiation efforts by providing the Claimant with cost breakdowns, explaining the cost-sharing method, and keeping the Claimant informed about the progress of the dossier preparation when requested.[6] In addition, they justified the use of the Fleischer list by referring to common practice and to the Directors Contact Group publication.[7]

39. However, the Other Party did not reply to the Claimant's requests for other details of the studies, such as year and laboratory quotation, nor did they provide an explanation on why such information could not be shared. Furthermore, they outright rejected the suggestion to adjust the study costs according to Klimisch reliability and other value elements of the studies, instead of entering into a constructive discussion with the Claimant.[8]

40. The Claimant made efforts by asking questions about the studies and study costs, and by explaining why they need the information, referring to the Implementing Regulation 2016/9 and ECHA's Guidance on data-sharing to justify their arguments.[9] By not providing or explaining the valuation elements of studies, by not explaining cost reductions they considered, nor explaining why this information could not be provided, when challenged by the Claimant, the Other Party did not enable the Claimant to evaluate whether the proposed cost was justified or not, and did not make every effort to reach an agreement. Furthermore, the Other Party refused to change the LoA, because it '*would be unfair to all already existing REACH co-registrants of the substances where [the Other Party] is lead registrant*'[10] instead of justifying why their cost sharing model was fair, transparent and non-discriminatory regarding this particular substance. Therefore, the parties could not reach a common understanding of the value of the studies, and the negotiations could not progress.

41. The Claimant made it clear, from the beginning of the negotiations, that Annex [redacted] was of particular interest to them, and that their intention was to register by 31 May 2018.[11] In this respect, the Other Party could have been more transparent and cooperative: it was only roughly one and half months before the registration deadline, and after several months of negotiations, that the cost sharing model for read-across endpoints was presented as being '*completely separate*' from other cost sharing.[12] This effectively did not leave the Claimant

[5] The Claimant; 25 April 2018
[6] The Other Party; 13 April 2018, 16 April 2018, and 27 April 2018
[7] The Other Party; 9 May 2018
[8] The Other Party; 9 May 2018
[9] The Claimant; 25 April 2018 and 3 May 2018
[10] The Other Party; 9 May 2018
[11] The Claimant; 4 January 2017, 4 July 2017, and 25 July 2017
[12] The Other Party; 16 April 2018

[redacted]

enough time e.g. to consider alternative ways to obtain the data before the registration deadline of 31 May 2018.

42. While it is true that neither REACH nor the Implementing Regulation 2016/9 establish the obligation to share data and its costs between different substances, the Other Party must act as a reliable negotiation partner to make every effort. In this regard, the Other Party did not make every effort to be transparent and predictable, failing to take into account the Claimant's objective situation.

On data ownership

43. As described above, the Claimant repeatedly requested to be actively involved in assessing data gaps and compiling the dossier in relation to the tonnage band [redacted], and to become a '*data owner of the new generate[d] data for a general interest*', asking in several occasions the Other Party to include this in the contracts between the parties.[13] In July 2017, the Claimant also asked the Other Party to propose how to proceed with the cooperation, for example a '*specific contract, organisation*', and suggested three different cooperation models.[14] Moreover, the Claimant asked to receive a new SIEF agreement for a '*Lead Member*' position in October 2017.[15]

44. ECHA notes, however, that the Other Party did not reply to the questions on cooperation models, nor did they comment on the Claimant's proposals, but only confirmed they would prepare a dossier for [redacted]tpa tonnage band as the Lead registrant.[16] Further, the Other Party did not reply to the request for a new SIEF agreement, but only shared their testing strategy and data gap analyses in October 2017.[17] To the Claimant's interest to become a co-owner, the Other Party replied in August 2017 that they would '*draft a data sharing agreement […] taking into account [the Claimant's] interest of equal rights of use*'.[18]

45. Nonetheless, when pressed by the Claimant in this respect in 2018, the Other Party argued that '*[a]s a matter of fact [the Other Party] is the lead registrant […and] [t]here is neither a consortium or a cooperation agreement in place*' and that '*[o]nly [the Other Party] is or will be the owner of the studies*'.[19] The Other Party further argued that only the Lead Registrant could have a leading role, and that the Claimant could either get access to the studies for REACH registration purposes or global registration purposes.[20] The Other Party did not provide any further explanations or justifications during the negotiations, merely asking the Claimant to indicate which of the proposed options they would choose.[21]

46. ECHA observes that the Other Party did inform the Claimant about their registration strategy and the progress with the dossier preparation. In addition, both parties made efforts to discuss a registration timeline, and the Claimant in particular set deadlines for replies. However, the Other Party was not a consistent and transparent negotiation partner, as only after several months of negotiation (April 2018) did they state that, in reality, only they could have a leading role, and that there was no contractual basis for cooperation.

47. While organising the work in the SIEF is the sole responsibility of the SIEF participants, they have the obligation to make every effort to reach an agreement on registering together and sharing data for that purpose. ECHA notes that the Other Party never made clear that

[13] The Claimant; 28 July 2017, 28 August 2017, 2 October 2017
[14] The Claimant; 17 July 2017
[15] The Claimant; 2 October 2017
[16] The Other Party; 1 August 2017
[17] The Other Party; 12 October 2017
[18] The Other Party; 1 August 2017
[19] The Other Party; 16 April 2018
[20] The Other Party, 9 May 2018
[21] The Other Party; 28 May 2018

[redacted]

having a contractual agreement was a prerequisite for cooperation, and did not reply to the Claimant's enquiry about cooperation models in July 2017, or to the Claimant's requests to become a 'Lead Member'.

48. Furthermore, by saying, in August 2017, that they would draft an agreement with '*equal rights of use*', the Other Party seemed to indicate that co-ownership of studies would be possible. In April 2018, conversely, they declared that only they could be the owner. Even in the absence of a contractual cooperation agreement, both parties had the obligation to act as reliable negotiation partners in a consistent and predictable manner, which the Other Party failed to do.

49. ECHA notes that the Claimant could have been more consistent in the requests for data-ownership. However, the Other Party's failure to consider the Claimant's requests or to negotiate the terms and conditions on access to their data virtually prevented both parties from reaching a mutual agreement, and caused the negotiations to reach a standstill.

50. In light of the above, ECHA considers that the Other Party did not make every effort to reach an agreement with the Claimant on how they would cooperate in registering together.

D. Conclusion

51. The Claimant made every effort to reach an agreement on access to the joint submission and the sharing of information, in particular by requesting information on studies and justification of study costs in light of the Implementing Regulation 2016/9. By refusing to provide the requested information and justification of costs, by not explaining why the information could not be provided, by not behaving in a consistent and transparent manner and by not taking the Claimant's position or requests into consideration, the Other Party effectively prevented the negotiations from progressing. Therefore, they did not fulfil their obligation to make every effort to find an agreement on data sharing in a fair, transparent and non-discriminatory way, as required by the Implementing Regulation 2016/9.

52. Consequently, ECHA can give the Claimant a permission to refer to existing studies subject to the negotiations, if they have been submitted, in accordance with Article 30(3) REACH.

53. However, not all the studies subject to the negotiations have been submitted yet. The Other Party has applied for DCG solution issue 10.3,[22] explaining that some studies do not exist yet and that the performance of the studies is delayed. The Other Party has demonstrated to ECHA that the relevant studies are being conducted. ECHA has thus requested the Other Party to submit the complete information by 31 January 2019.

54. Therefore, ECHA will grant the Claimant a permission to refer to the studies once they have been submitted to ECHA.

55. In case studies subject to the negotiations will not be submitted by 31 January 2019, ECHA may, depending on whether the studies exist, take a decision allowing the Claimant to carry out the studies in accordance with Article 30(2) REACH or to proceed with registration in accordance with Article 30(3) REACH.

[22] ECHA Director's Contact Group issue 10.3 "Completeness of registration dossiers – Data required in Annexes VII and VIII of REACH not yet available by the registration deadline" (https://echa.europa.eu/fi/about-us/partners-and-networks/directors-contact-group/dcg-issues).