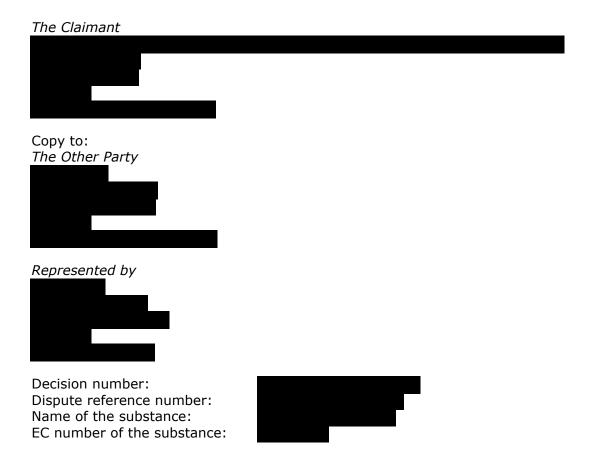




Helsinki, 20 February 2017



DECISION ON A DISPUTE

a) Decision

Based on Article 19 of Regulation (EC) No 1907/2006 ('REACH Regulation') 1 and Article 3 of the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH ('Commission Implementing Regulation') 2 ,

ECHA grants you access to the joint submission requested from

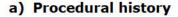
The reasons of this decision are set out in Annex I. The factual background of the dispute is described in Annex II. The instructions on how to submit your registration dossier are provided in Annex III.

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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.





On 24 November 2016, you ('the Claimant') submitted a claim concerning the failure to reach an agreement on the access to the joint submission with represented by ('the Other Party') as well as the related documentary evidence to ECHA. To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA also requested the Other Party to provide documentary evidence regarding the negotiations. The Other Party submitted the documentary evidence on 6 December 2016.

b) Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to the Board of Appeal of ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/web/quest/regulations/appeals.

c) Advice and further observations

ECHA reminds both parties that in spite of 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.

Yours sincerely,

Christel Schilliger-Musset³

Director of Registration

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³ 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 OF THE DECISION

According to Article 19 of the REACH Regulation, all registrants of the same intermediate are part of the same registration under REACH ('joint submission of data'). Further, Article 3(1) of the Commission Implementing Regulation requires ECHA to ensure that all registrants of the same substance are part of the same registration for the substance.

Article 3(3) of the Commission Implementing Regulation also confirms that a potential registrant may decide to invoke Article 19(2) of REACH in order to submit separately all or part of the relevant information in Article 10(a) of REACH. Before doing so however, the potential registrant is required to ensure that he has complied with his obligations under Articles 26 or 29 of REACH and has ascertained that he is not required to share tests on vertebrate animals for the purposes of his registration.

In such cases, Article 3(3) of the Commission Implementing Regulation requires ECHA, upon the potential registrant's request, to ensure that this separate submission of information remains part of the existing registration for the substance. The parties have to make every effort to be part of the same joint submission. It follows that in case of a failure to reach an agreement on the access to the joint submission the possibility is given to the potential registrant to submit a dispute to ECHA.

A dispute brought to ECHA in that context requires the Agency to determine whether to grant access to the joint submission. In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the documentary evidence on the negotiations as provided by the parties, to establish whether the parties made every effort to reach an agreement on the conditions for access to the joint submission.

Factual background

The Claimant initiated the negotiations on 26 April 2016 and asked for the LoA (Letter of Access) price for their intermediate registration in a tonnage band tpa⁴.

In their reply, the Other Party wrote that the LoA price was currently being revised but that it would be available soon. They also requested the Claimant to pay entry fee' before providing the SIEF agreement, followed by the LoA invoice and ultimately the provision of the token⁵. Subsequently they informed that the LoA price would be EUR for the requested registration type, based on 'Consulting costs' of EUR, 'External SIEF management costs' of EUR, and 'Lead Registrant management costs' of EUR, divided between the two registrants⁶.

The Claimant disagreed with the 'very high' LoA price and asked for more detailed explanations about 'incomprehensible' cost items and a transparent itemisation in accordance with the Commission Implementing Regulation⁷.

In the following, the discussions between the parties related to clarifying the incurred costs.

With reference to the limited information requirements applicable to intermediate registrations in a volume under strictly controlled conditions, the Claimant

⁵ See reference no. 4

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⁴ See reference no. 3

⁶ See reference no. 5

⁷ See reference no. 6



disagreed with the cost proposal⁸, and repeatedly requested a meaningful cost breakdown to be able to assess the LoA price⁹ without paying any 'Entry Fee'¹⁰. They further stated that the 'Cost Allocation was merely a generic document but did not allow them to understand the actually incurred costs for this substance¹¹. They specifically challenged the 'Lead Registrant management costs' and requested further justification for these costs¹².

On the other hand, the Other Party wrote that 'study costs are [...] not charged'¹³ but that the dossier was 'rather comprehensive'¹⁴ and went 'far beyond the usual literature data'¹⁵ for intermediate registrations, as a consultant had conducted a 'literature research and [...] expert assessment' to 'provide robust study data' and include it in the lead dossier¹⁶. They provided a document a 'a immed to describe 'as far as possible all individual cost items that may occur'. 'Before providing further information, however, they asked the Claimant to pay the 'Entry Fee'¹⁸. They also suggested that the Claimant could review the invoices at their premises¹⁹, and upon the Claimant's request, stated that the cost item 'Lead Registrant management costs' related to their own internal work²⁰.

Further, the Claimant sought clarifications from ECHA during the process of the negotiations²¹. However, as ECHA assesses the efforts made by the parties in their negotiations, it does not take unilateral contacts between one of the parties and ECHA into account in the assessment of the dispute.

Assessment

A potential registrant, such as the Claimant, has the right to receive an itemisation of the requested compensation for access to data and/or the joint submission, in accordance with the requirements of Article 30 of REACH and Articles 2 and 4 of the Commission Implementing Regulation. Accordingly, such an itemisation needs to list cost items not only related to data (if applicable), but also related to administrative and future costs. It also needs to include justifications for each cost item.²² This information is essential to enable a potential registrant to assess whether the requested compensation for access to data and/or to the joint submission is fair, transparent and non-discriminatory as required by REACH and the Commission Implementing Regulation.

As outlined above, it is the Claimant's right to receive such an itemisation. Accordingly, the Claimant made seven requests between end of May 2016 and end of November 2016 to receive a cost breakdown that would enable them to understand the requested price. They thereby made every effort to proceed with the negotiations.

⁸ See reference no. 20, 22

⁹ See references no. 6, 8, 12, 18, 20, 22 and 30

¹⁰ See references no. 10, 13, 18

¹¹ See references no. 8, 18, 22

¹² See reference no. 8, 20, 22

¹³ See reference no. 10

¹⁴ See reference no. 7

¹⁵ See reference no. 10

¹⁶ See reference no. 21

¹⁷ See reference no. 7

¹⁸ See references no. 10, 12 and 19

¹⁹ See references no. 19, 21 and 23

²⁰ See reference no. 21

²¹ See reference no. 25 - 34

²² See Guidance on data sharing, chapter 5 *Cost sharing*, available at https://echa.europa.eu/quidance-documents/quidance-on-reach



However, the information provided by the Other Party did not enable the Claimant to understand the price calculation. Namely, the Other Party only indicated overall sums per cost heading; they did not justify or break down further the actual cost elements and sums. This related e.g. to consultancy and 'Lead Registrant management', with the latter accounting for nearly half of the total costs.

Further, setting preconditions for receiving information that would be crucial to understand the cost calculation, is irreconcilable with the Claimant's right under REACH and the Commission Implementing Regulation to receive a cost itemisation. By requesting the Claimant to pay an 'Entry Fee', the Other Party prevented the Claimant from receiving a meaningful cost itemisation²³. In the same vein, the Other Party created an additional hurdle to assess the price by only allowing a review of the invoices for the consultant's work at their own premises without providing a justification.

Without this information, the Claimant was not able to understand and validate the incurred expenses. Consequently, the Other Party prevented them from reaching an agreement on the costs for participation in the joint submission, and thereby failed to comply with the obligation to make every effort to share the incurred costs in a fair, transparent and non-discriminatory manner.

Further, based on Article 18 of REACH, the information requirements for intermediates in a tonnage band are limited to 'any available existing information on physicochemical, human health or environmental properties of the intermediate', if the substance is handled under strictly controlled conditions. This is made explicit in Article REACH, which lists the information that registrants of a intermediate under strictly controlled conditions must provide in their registration. They only need to provide information on physicochemical, human health or environmental properties that is available to them. This means that they need to prepare their registration dossier which only provides such information that is available to them at no additional cost. In the words of the Guidance on data sharing²⁴, such registrants 'are largely exempt from the obligation to submit the standard information specified in Annexes Therefore, it is clarified further that such registrants 'cannot be forced to share in the joint submission costs related to the data they don't need (registrants of intermediates are only required to submit any information available to them for free). Intermediate registrants might still be required to pay those administrative costs that relate to the creation and administration of the joint submission as such. However, it can be reasonably expected that these costs are rather low. 25

Accordingly, the parties were in agreement that no data would need to be shared for this registration type. However, the Other Party requested the Claimant to participate in the consultancy costs, which included the scientific assessment of literature and studies and incorporating these in the Other Party's registration dossier. Hence, the Other Party requested the Claimant to share costs, which are not related to the joint submission as such, as the Claimant pointed out in their reply. Tolerated the parties had agreed not to share data, requesting the Claimant to share into dossier preparation related costs is in breach of the obligation to make every effort to reach a fair agreement.

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²³ See also "Practical advice for data sharing negotiations", section 4 "Request a cost-breakdown", available at: https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations
²⁴ See Guidance on data sharing, chapter 6.2 *Intermediates under strictly controlled conditions*, available at

https://echa.europa.eu/guidance-documents/guidance-on-reach

²⁵ Ibidem

²⁶ See reference no. 21

²⁷ See reference no. 22



Conclusion

Based on the above, ECHA concludes that the Claimant made every effort to reach an agreement on the access to the joint submission in a fair and transparent way while the Other Party did not.

Consequently, ECHA grants the Claimant access to the joint submission for the substance subject to this dispute. This does not allow the Claimant to rely on any of the data submitted in the joint dossier.



Annex II: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

| Ref. no. | Date | Content | Remark |
|----------|------------|---|---|
| 1. | 20/10/2014 | The Other Party communicates to the SIEF 'on behalf of a SIEF Facilitator', stating that they are 'possessing considerable numbers of data' and are 'preparing a lead dossier (intermediate use)'. They ask the other potential registrants to fill out a questionnaire, and announce they would like to start discussing substance sameness, elect a lead registrant, and get an overview of the available data. | Only provided by the Other Party |
| 2. | 06/11/2014 | The Other Party reminds of their earlier communication and of the deadline of 14/11/2014 to reply to the questionnaire. | Only provided by the Other Party |
| 3. | 14/04/2016 | The Claimant initiates the discussions, contacts the lead registrant and asks for `costs and conditions of a participation in the already existing registration' for their registration as `Intermediate for the tonnage band /year'. | |
| 4. | 26/04/2016 | The Other Party replies and informs that they are 'the SIEF Manager on behalf of [the lead registrant]'. They further write that they 'are currently revising the costing [and] will be able soon to give [] an indication of the current costs for the Letter of Access' for the Claimant's registration type. They attach the substance identity profile and inform about the process for registration: They will provide 'the current LoA cost estimate as soon as the costing is ready'; if the Claimant decides to register, they will issue 'a first invoice on the entry fee (EUR) which will be balanced later on with the LoA invoice'; following payment, the Claimant 'will receive the SIEF Agreement'; after signature of the SIEF agreement, they will issue the 'LoA invoice'; and 'once paid, [the Claimant] will receive the Member Dossier, Security Token and the signed Letter of Access'. | Substance identity profile not provided to ECHA |



| Ref. no. | Date | Content | Remark |
|----------|------------|--|--------|
| 5. | 03/05/2016 | The Other Party sends the LoA costs, quoting They also provide a list of cost items: Under 'Total costs', they list for Intermediate of EUR, 'External SIEF management costs' of EUR, 'Lead Registrant management costs' of EUR and 'Total Study Values' of EUR. Under 'Costs per registrant', they calculate a 'Total costs per Member Registrant' of EUR for an intermediate registration. Finally, they point to the upcoming change from IUCLID version 5, highlighting that 'it will take a while to convert the dossier to IUCLID [version] 6 before it will be made available to Member Registrants'. | * |
| 6. | 25/05/2016 | The Claimant replies that the costs 'seem very high for a registration as intermediate', and asks for a more detailed explanation about the individual cost items. With reference to their experience with other registrations, they write that consultation costs and EUR lead registrant management costs are 'incomprehensible' for them and ask the Other Party to specify the work done under external SIEF management costs. Finally, with reference to the Commission Implementing Regulation on joint submission of data and data sharing, they request a transparent cost itemisation. | * |
| 7. | 06/06/2016 | The Other Party states that their dossier is 'rather comprehensive' for an intermediate registration and sends the link to the information disseminated on ECHA's homepage. Further, they send a document 'general ', which is supposed to explain 'as far as possible all individual cost items that may occur', and inform that this document in combination with their email of 03/05/2016 fulfils from their point of view the requirements for a transparent cost itemisation. Finally, they inform that they can proof with invoices the costs related to external consultants. | * |
| 8. | 21/06/2016 | The Claimant writes that the actual registration work done for the substance in question cannot be understood from the 'decument' document. Therefore, they request insight into | * |



| Ref. no. | Date | Content | Remark |
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| | | the work done by the consultant. Further, they request more details on the charged as `Lead Registrant management cost', as this would equate hours at a rate of EUR/hour. | |
| 9. | 24/06/2016 | The Other Party informs that they have passed on the question to the lead registrant, as they did not prepare the dossier themselves. | * |
| 10. | 08/07/2016 | The Other Party asks the Claimant to pay a efforts' and to cover the expenses related to the SIEF work in case the Claimant should not be interested in the end. Like this, they would avoid charging other SIEF members for dealing with LoA requests. They further inform that the 'Entry Fee' would be deducted from the final LoA price should the Claimant chose to buy the LoA. They also write that the lead registrant is 'of course willing' to clarify their own and the consultant's efforts. They advise again to consult ECHA's dissemination portal to get familiar with the content of their dossier, writing that it 'goes far beyond the usual literature data' for intermediate registrations, and stating that 'study costs are [] not charged, as this is not commonly done for intermediates'. | * |
| 11. | 11/07/2016 | The Claimant confirms their interest in the joint submission and provides their invoicing data. In addition, they request to receive the SIEF and data sharing contract `before payment of the invoice'. | * |
| 12. | 22/07/2016 | The Other Party provides the 'general template of the SIEF agreement', which is 'based on the CEFIC template and has been tailored according to [the lead registrant's] to which the company details and substance information as well as the list of cost items provided in their email of 03/05/2016 will be added. They request confirmation whether the invoice can be issued, stating that 'from [the other party's] side no further action will be taken before that' [i.e., before issuing the invoice for the entry fee]. | * |



| Ref. no. | Date | Content | Remark |
|----------|------------|---|--------|
| 13. | 22/07/2016 | The Claimant writes that the SIEF agreement does not comply with the itemisation requirement of the Commission Implementing Regulation on joint submission of data and data sharing, and that it does not allow to understand the LoA costs. Further, they state that 'before concluding the SIEF contract, [they] would like to know which costs they can expect'. The Claimant writes further that their legal department has 'strong reservations when cost details and itemisation of the incurred costs are made dependent on previous payment of an entry fee'. With reference to a document issued by the German Helpdesk, they point out that they 'cannot be forced to pay a deposit or a fee, or to sign a secrecy agreement, before receiving the cost itemisation'. Therefore, they request a detailed account of the cost incurred for SIEF management and consultancy, and state that before receiving this information they 'cannot sign an agreement and would be forced to inform ECHA about this'. Finally, they state that the 'slightly modified CEFIC template' cannot have incurred significant costs, and offer to provide a SIEF agreement which has been revised in light of the Commission Implementing Regulation. | * |
| 14. | 09/08/2016 | The Other Party proposes to discuss further in a conference call, and proposes possible dates: 18/08/2016 or 19/08/2016. | * |
| 15. | 16/08/2016 | The Other Party asks for confirmation about the conference call. | * |
| 16. | 16/08/2016 | The Claimant accepts the offer to have a conference call on 18/08/2016. | * |
| 17. | 16/08/2016 | The Other Party confirms the conference call. | * |
| 18. | 05/09/2016 | The Claimant requests a 'fair and transparent itemisation of the incurred costs', with reference to the request made in the phone call of 18/08/2016. They state that the current itemisation, which lists 'Consulting costs' EUR), 'External Management costs' EUR), and 'Lead Registrant management costs' EUR), is 'not sufficient'. They write that costs of EUR for dossier preparation and dealing with possible requests from other SIEF members are 'clearly too high', and that the stays on a very general | * |



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| Ref. no. | Date | Content | Remark |
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| | | level, and doesn't allow to understand how the high sum has incurred in the present case'. They further state that 'it doesn't exactly inspire confidence' that the Other Party has not followed up on their announcement to prove the costs related to consultants by providing the invoices. Finally, 'according to the principle of transparency' they 'insist on their right to receive a detailed cost itemisation without previous payment of the requested entry fee', setting a deadline of 23/09/2016 to receive this information. Otherwise, they inform that they 'will refer the matter to ECHA'. | |
| 19. | 06/09/2016 | The Other Party understands that the Claimant 'mistrusts the dossiers costs that have incurred so far'. With reference to their conference call of 18/08/2016, they write that they have 'followed the principle of transparency' and explained the reasons for the 'relatively high dossier costs'. Further, they state that the Claimant had committed to 'submit in writing any further unclear issues and requests for further substantiation' by week 34, but had not done so. To 'solve the current conflict', they make three alternative suggestions: (i) the Claimant can review the invoices at the Other Party's premises; (ii) the Claimant pays the 'Entry Fee' to proceed with the LoA discussions according to the terms outlined by the Other Party; (iii) the Claimant takes over the lead registrants role 'including SIEF communication and LoA sales' after compensation to the Other Party | * |
| 20. | 08/09/2016 | The Claimant lists the information about the Other Party's dossier retrieved form ECHA's dissemination page, and writes that the 'number of actually performed studies is somewhat limited'. Further, they ask 'why [the Other Party] have made such research efforts for an intermediate registration. This is not necessary for such a registration and cannot justify the high costs (Consulting costs EUR) incurred for the dossier preparation'. They request information about the actual lead registrant management cost, including the work incurred to deal with requests from other SIEF members, during the last 2 years, as well as information about the result of the SIEF survey conducted by the Other Party in 2014. | * |



| Ref. no. | Date | Content | Remark |
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| | | Further, they write that they do not intend to review the invoices at the Other Party's premises, as 'copies or pdf files [] seem sufficient' for this purpose. Finally, they state that they are willing to 'consider the offer to take over the [lead registrant] role' and ask the Other Party to provide an 'adequate cost quotation' for such a transfer of the lead registrant role 'based on the situation of the data and the data requirements' | |
| 21. | 09/09/2016 | The Other Party writes that they have 'included all available data including own studies (which were available before the registration) in the registration dossier'. They highlight that 'no new studies have been performed' (emphasis by the Other Party), and write that the work relates to the consultant's 'expert assessment and dossier preparation', stating that they aim to 'provide robust data in the dossier' for which it is essential to conduct an 'appropriate literature research and, following an expert assessment, to take into account relevant literature'. Concerning the lead registrant management cost, they write that these relate to the lead registrant's 'internal efforts (and not [] SIEF work invoiced by [the consultant])'. Further, they state that the Claimant did not react to the SIEF survey but contacted them 'nearly one year' after the Other Party had submitted the dossier. They inform that they 'will not provide [invoices as] pdf files' and repeat their offer to make the invoices available for a review at their site. Concerning the possibility that the Claimant would take over the lead role, they write that the Claimant 'would have to register as a member first' before the lead role could be transferred, while the 'necessary contracts and costs of course need to be clarified beforehand'. | * |
| 22. | 16/09/2016 | The Claimant writes their 'intention was and is, to understand the quoted total costs. Unfortunately, despite repeated requests, no conclusive explanation was given'. They summarise the 'received information and [their] conclusions': - The consultant has been commissioned to make a data analysis and to prepare the dossier; the Other Party intends to charge potential registrants for these costs. While 'honouring the efforts to deliver robust data', they refer to the requirement to provide only 'available data' and write that such efforts are not required for an intermediate registration. Therefore, they 'don't want to share these costs'. | * |



| Ref. no. | Date | Content | Remark |
|----------|------------|---|--------|
| | | - Regarding the external management costs, they state that 'no further explanations' have been provided other than a generic explanation in the (which refers to 'support on financial and administration related matters'). Further, they point out that practice shows that 'a review of the invoices is made dependent on personal inspection of files and on previous payment of an entry fee', while this limitation of access is not mentioned in the document. Finally, with a view to the lead registrant management costs, they write that these costs 'during four months of discussion have not been specified nor proven', and that 'without further explanations about how it has been accrued, [they] don't want to participate in this amount'. | |
| 23. | 23/09/2016 | The Other Party writes to 'summarise some of the discussion points', stating they have 'endeavoured several times to break down all the incurred costs' even though these costs have incurred 'before the [Commission Implementing Regulation on joint submission of data and data sharing]'. They further write that the Claimant has 'rejected' the offer to review the invoices at the Other Party's premises, and that they 'cannot provide all company internal invoices in pdf format via email'. Further, they again send a list of 'All incurred costs', as mentioned in their email of 03/05/2016, with corrections to the external SIEF management costs 'from EUR' to EUR'. | |
| 24. | 28/09/2016 | The Claimant writes that their `mistrust concerning the dossier costs' persists, and that they therefore `want to make use of their right to separately submit' their dossier. Therefore, they request the Other Party to `provide the token for the joint submission'. | * |
| 25. | 05/10/2016 | The Other Party states they 'regret' that the Claimant wants to pursue this approach, and that they are 'are glad to participate in a common discussion on this issue with ECHA, to reach a mutual agreement. After that, [they] hope to have clarity concerning the approach'. | * |



| Ref. no. | Date | Content | Remark |
|----------|------------|---|---|
| 26. | 05/10/2016 | The Claimant 'welcomes [the Other Party's] availability to commonly discuss with ECHA'. They repeat their request to receive the token and announce to inform ECHA 'outside REACH-IT' should they not receive access to the joint submission by 12/10/2016. | * |
| 27. | 07/10/2016 | The Other Party replies that the CAS and/or EC number is sufficient to inform ECHA. | * |
| 28. | 13/10/2016 | The Claimant provides an attachment with `today's notification to ECHA'. | * Attachment not enclosed to evidence |
| 29. | 14/10/2016 | The Other Party confirms receipt. | Only provided by the Other Party |
| 30. | 21/11/2016 | The Claimant writes that they received information from ECHA that also the Other Party 'has been informed, to actively participate in the data-sharing dispute'. They 'want to give the opportunity, to make an alternative offer for fair and transparent sharing of the actually incurred registration costs'. Finally, they inform that they will lodge the data-sharing dispute at ECHA if they have not heard back from the Other Party by 23/11/2016. | * |
| 31. | 21/11/2016 | The Other Party informs that they have not received any information from ECHA and ask for a reference number. | * |
| 32. | 22/11/2016 | The Claimant attaches the communication from ECHA including the reference number. | Attachment not enclosed to |



| Ref. no. | Date | Content | Remark |
|----------|------------|--|----------|
| | | | evidence |
| 33. | 22/11/2016 | The Other Party confirms receipt. | * |
| 34. | 23/11/2016 | The Other Party informs that they `want to wait for the official communication from ECHA' before discussing further steps in the data-sharing dispute. | |

^{*}Negotiations conducted in language. The summary of communications between parties is based on ECHA own translations (including quotes) and is not a literal reproduction of the submitted documentation.

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