[redacted]

12 April 2016

[redacted]

Sent via REACH IT

Copy to Other Party*:*

[redacted]

By email only

Reference number of the dispute claim	[redacted]
Decision number	[redacted]
Names and EC numbers of the substances	[redacted]

[redacted]

DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 30(3) OF THE REACH REGULATION (EC) No 1907/2006

Dear [redacted],

On 25 January 2016, [redacted] (hereinafter referred to as 'the Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with [redacted] (hereinafter referred to as 'the Other Party') as well as the related documentary evidence to the European Chemicals Agency (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 requested documentary evidence on 11 February 2016.

Based on the documentation supplied by both parties, ECHA has decided not to grant you permission to refer to the studies requested from the Other Party for the above-mentioned substances.

The statement of reasons regarding the assessment of the data sharing dispute is set out in Annex I. General recommendations for further data sharing negotiations are provided in Annex II to this decision while the factual background regarding the data sharing negotiations can be found in Annex III.

In accordance with Article 30(5) of the REACH Regulation, both parties involved in the dispute may appeal against this decision to the Board of Appeal of ECHA within three months of the notification of this decision. The procedure for lodging an appeal is described at http://echa.europa.eu/web/guest/regulations/appeals.

Yours sincerely,

Christel Musset
Director of Registration

Annexes:

Annex I: Statement of reasons regarding the assessment of the data sharing dispute

Annex II: General recommendations

Annex III: Factual background regarding the data sharing negotiations

[redacted]

Annex I to decision [redacted]

STATEMENT OF REASONS REGARDING THE ASSESSMENT OF THE DATA SHARING DISPUTE

Pursuant to Article 30(1) of the REACH Regulation, *"Within one month of the request, the owner of the study shall provide proof of its cost to the* [SIEF] *participant(s) requesting it. The participant(s) and the owner* [of the data] *shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way*". In case of a dispute on the sharing of studies involving vertebrate animal testing already submitted by another registrant, Article 30(3) of the REACH Regulation requires ECHA to determine whether to grant a permission to refer to the information contained in the registration dossier, *i.e.* to the corresponding studies. In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of the documentary evidence on the negotiations as provided by the parties, so as to establish whether the parties have made every effort to reach an agreement on the sharing of studies and their costs in a fair, transparent and non-discriminatory way.

Accordingly, following the lodging of the dispute claim by the Claimant on 25 January 2016, ECHA conducted an assessment serving to establish whether the parties have fulfilled their legal obligation to make every effort to share the studies and their related costs fairly, transparently and non-discriminatively. The assessment is based on the information provided by the Claimant and the Other Party. An overview can be found in Annex III to this decision.

In order to make every effort to reach an agreement, the parties shall negotiate the sharing of data and related costs as constructively as possible to make sure that the negotiations move forward by expressing their arguments and concerns, and replying and asking relevant questions. Notably, they should take into account the information they have received from the other party and use it effectively in order to find a common understanding on which the data and cost sharing agreement can ultimately be based upon.

The dispute at hand concerns the negotiations that took place between the parties after ECHA notified to them on 22 July 2015 its decision with reference number [redacted] on the dispute claim lodged by the Claimant on 28 April 2015 (the "previous decision"). That dispute claim concerned the parties' negotiations between 7 August 2014 and 28 April 2015. In its previous decision, ECHA concluded that the Claimant did not make every effort to reach an agreement with the Other Party and thus it did not grant it the permission to refer to the Other Party's data. It was pointed out that the Claimant insisted throughout the negotiations on receiving the costs of the individual studies by the Other Party, although the latter clarified that it was not mandated to negotiate access to the individual studies included in the joint registration. The Other Party explained that it was only entitled to carry out the initial communications with potential registrants in relation to their access to the existing joint submission based on the agreed, between the existing registrants, data and cost sharing model of the category approach. The Claimant refused to get in contact, with the help of the Other Party, with the respective data owners although, as ECHA indicated in the previous decision, "[r]*equesting the contact details of the data*

[redacted]

owners and entering into negotiations with the latter could have enabled the Claimant to receive the proof of the study costs and thus effectively exercise its rights under Article 30(1) of REACH".[1] It was also noted that the Other Party should have been more proactive in facilitating the contacts between the Claimant and the respective data owners.

ECHA acknowledges that both parties have taken into consideration in their subsequent negotiations[2] the remarks made by ECHA in its previous decision. From its side, the Claimant expressed to the Other Party its interest to get in touch with the data owners of the substances of interest.[3] From its side, the Other Party helped the Claimant to get in contact with the respective data owners.[4]

During the subsequent negotiations of the parties, the Claimant clarified that it was not interested in negotiating access to each study separately with their respective owners. Instead, the Claimant pointed out that it was interested in receiving information on the cost of each individual study that a co-registrant has to share in the context of the joint registration for the substances.[5] In response, the Other Party provided detailed explanations on the data and cost sharing model of the category approach on which the joint registration of the substances has been based.[6] The Other Party clarified that the value of a study included in the joint registration dossier "[..]*is shared between all the registrations in the group at the relevant tonnage band. Since all the data for all the substances in the category/group supports the category approach, all the studies are considered together as a group according to their applicable annex* [of REACH] *and the total cost divided between all the registrants (according to the tonnage of the registration)*".[7] The Other Party added that "[a]*s a consequence co-registrants only share in the cost of data related to the Annex at which they are registering. This will include the studies directly summarized in their dossier and studies which may not be entered as study summaries but which are nevertheless summarized and referenced in the category justification. Since the category justification is dependent upon all the studies, it is right and proper that all registrants who rely on the justification should share the costs of the studies*".[8] The Other Party repeatedly offered to explain to the Claimant the details of the cost sharing model by telephone with the help of screen sharing.[9] The Claimant however declined that offer arguing that it preferred to communicate only in writing.[10]

Notwithstanding the abovementioned explanations of the Other Party, the Claimant insisted throughout the negotiations that the Other Party failed to provide transparent information on the costs of the individual studies that each co-registrant has to share and that, as a

[1] See ECHA's decision [redacted] pages 7-8.
[2] i.e. the parties' negotiations after 22 July 2015, i.e. the date when ECHA notified to the parties the previous decision.
[3] See reference nos. 1 and 7.
[4] See reference nos. 2 and 8.
[5] See reference no. 26.
[6] See reference nos. 15 and 17.
[7] See reference no. 15.
[8] See reference no. 17.
[9] See reference nos. 8, 15 and 17.
[10] See reference nos. 9 and 16.

consequence, the Claimant is requested to pay "a generic fee" for the data contained in the joint registration dossier.[11] Moreover, the Claimant argued that the cost sharing model is unfair "[..]*as it does not contain any fair provision to allow a potential co-registant to opt-out certain studies if not under the unfair condition (as emerged by correspondence with Data Owners) of paying 100% of the cost of non opted out studies, where there are several other registrants and the cost of such non opted out studies could be equally shared by all*".[12] In its previous decision, ECHA stated that, due to the way a category approach is developed, "[i]*f a registrant wishes to opt out from the category approach, he should specify from the bulk of studies supporting the category, which particular study he intends to refer to separately for his specific substance*".[13] However, the Claimant failed to take into consideration in its negotiations with the Other Party ECHA's remark, despite the fact that the Other Party repeatedly requested the Claimant to specify the studies it would like to opt out from.[14]

Nevertheless, in an effort to unblock the negotiations between the parties, the Other Party proposed alternative strategies to the Claimant for submitting an opt-out to the joint registration. The Other Party suggested to the Claimant that it can either develop its dossier on the basis of the data and cost sharing model of the category approach and opt out from certain studies of the joint submission dossier; or instead, develop a full opt-out dossier which will not be based on the data and cost sharing model of the category approach but it will nevertheless remain part of the joint submission.[15] The Claimant, however, did not follow up on these proposals.

As pointed out by ECHA in its previous decision, "[..]*the essence of the dossiers submitted for each substance covered by the category is to provide supporting evidence of the category, including theoretical considerations and results from studies performed on some of the substances of the category*".[16] This may result in a complex data and cost sharing model which nevertheless must be fair, transparent and non-discriminatory. The Other Party had already provided to the Claimant the cost breakdown per endpoint for the joint registration of the substances during the parties' negotiations that ECHA assessed in its previous decision.[17] During the parties' negotiations that form the subject of the present assessment, the Other Party provided further explanations on the data and cost sharing model that could enable the Claimant to understand the basis of the cost calculation for the Letter of Access (LoA) to the joint registration of the substances and thus help the parties to reach an agreement on the sharing of data and its costs. However, the Claimant did not engage in a constructive negotiation with the Other Party. Instead, throughout the parties' negotiations, it repeated that it did not receive the requested costs of the individual studies included in the joint registration for the substances. Moreover, the Claimant did not follow

[11] See reference nos. 7, 14, 16, 18 and 26.
[12] See reference no. 16.
[13] See ECHA's decision [redacted] page 7.
[14] See reference nos. 17 to 22.
[15] See reference no. 20.
[16] See ECHA's decision [redacted] page 7.
[17] See footnote 18 of ECHA's decision with reference number [redacted] on the dispute claim lodged by the Claimant on 28 April 2015.

[redacted]

up on the alternative strategies proposed by the Other Party in case it would choose to submit an opt-out.

The above demonstrates that the Claimant did not make every effort to reach an agreement with the Other Party. Consequently, ECHA cannot grant the Claimant a permission to refer to the requested information.

ECHA emphasises that both parties remain obliged to comply with their data sharing obligation to make every effort to reach an agreement after this decision. The parties are hence strongly encouraged to continue their negotiations taking into consideration this decision and the recommendations provided in the Annex II.

[redacted]

Annex II to decision [redacted]

GENERAL RECOMMENDATIONS FOR FURTHER DATA SHARING NEGOTIATIONS

ECHA would like to make some general observations in order to facilitate a future agreement:

- If a claimant aims to be part of a joint submission but does not agree with a chosen data and cost sharing model, the claimant should negotiate constructively with the other party and challenge with substantiated arguments the basis of the chosen model in terms of transparency, fairness and non-discrimination.

- Parties of data sharing negotiations should explore different options to unblock and advance the negotiations.

- Oral interactions between the parties can be documented in a written form that has been agreed by both parties. Oral interactions may help the parties to exchange more efficiently information on complex issues, such as the data and cost sharing model at hand.

- If the future data sharing negotiations would fail again, the Claimant is free to submit another claim, covering the efforts subsequent to the present decision;

- ECHA points out that correct and consistent communication between the parties involved is important so that misunderstandings can be avoided;

- ECHA is never a party in the negotiations. Therefore, all arguments have to be communicated between both parties directly. Any document, which has not been shared with the other party, cannot be taken into consideration in ECHA's assessment of the dispute claim;

- ECHA reminds both parties that the outcome of a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would. Accordingly, ECHA strongly encourages the parties to continue their efforts to reach an agreement that will be satisfactory for both parties.

[redacted]

Annex III to decision [redacted]

FACTUAL BACKGROUND REGARDING THE DATA SHARING NEGOTIATIONS

The following lists the exchanges between the parties, which have been provided by either or both of the parties and form the basis of ECHA's assessment of the dispute case.

Ref. Doc.	Date	Content	Remark
CORRESPONDENCE BETWEEN CLAIMANT, [redacted] AND DATA OWNERS			
1	23/07/2015	The Claimant asked [redacted] Representative [redacted] (hereinafter referred as "Consortium Representative") and the lead registrant of the substance with EC number [redacted] for contact details of the owners of the data contained in the lead dossier for substance with EC number [redacted] "*in order to receive proof of the study costs for the single registrant*".	
2	24/07/2015	The Consortium Representative forwarded Ref. Doc. 1 to the Data Owners and informed them that the Claimant wants to discuss individually with each of them. Furthermore, the Consortium Representative explained that "*[i]n respect of data protection and confidentiality issues, the Consortium Management will not disclose the identity of study owners to any 3rd party, rather [Consortium] will pass on requests from enquirers to data owners to follow up directly*". The Consortium Representative asked data owners to contact the Claimant "*to understand [Claimant's] request and to respond accordingly*". Finally, the Consortium Representative asked data owners to make their "*initial contact before Friday 7th August*". The Consortium Representative attached the "*data matrix for the dossier*" indicating "*the study valuation for studies which were compensated*". The Consortium Representative further stated that the Claimant had already received same information without identification of the study owners. The Consortium Representative stressed that the matter is delicate and suggested Data Owners "*to establish exactly what question [Claimant] requires answer's to*".	Data matrix only provided by the Other Party
3	24/07/2015	The Consortium Representative informed the Claimant, with the data owners of substance with EC number	

Ref. Doc.	Date	Content	Remark
		[redacted] in copy, that he has asked eight study owners to reply to Claimant by 07/08/2015.	
4	13/08/2015	The Claimant informed the Consortium Representative that three Data Owners had not replied.	
5	13/08/2015	The Consortium Representative promised to encourage the three Data Owners to reply.	
6	13/08/2015	The Consortium Representative asked the three data owners to open dialogue with the Claimant.	
7	18/09/2015	The Claimant informed the Consortium Representative that "*the open data sharing dispute does not regard[s] only substance* [redacted]" but also other eight substances with CAS numbers [redacted]. The Claimant stated that it had received most replies from the data owners of substance with CAS [redacted] and from the replies the Claimant concluded that 1. Data owners are not always lead registrants. 2. Data owners share a common position and offer data at the same total study cost mentioned in Consortium's cost breakdown dated 27/10/2014. Based on this position the Claimant saw two options: a. "*Accepting to pay a generic fee for the data contained in the joint registration dossier, without getting detailed information on the costs of the individual studies for the single co-registrant. (individual proportion according to 'Practical advice for data sharing negotiations' by ECHA point 7)*". b. "*Accepting to pay the whole cost of the study before repartition among the co-registrants. (whichever method of calculation has been used for repartition by [Consortium])*". The Claimant stated that it could not accept either of the options as it considered option a. not to be transparent as "*the data owner requests the payment of a generic fee*" whereas the option b. it considered not to be fair, "*in line with Guidance on Data Sharing – ECHA 2012 point 4.7.5*", as "*the data owner requests 100 % of the cost of the study where there are several other registrants and the cost could be shared by all*". 3. As the "*dealing with data owners is very time and energy expensive*", Claimant asked if the position of data owners of the other eight substances listed will be the same as for the substance with CAS number [redacted]. The Claimant requested the Consortium to put them in contact with the other data owners only if Consortium thinks that the approach of the owners of the data for the listed eight substances is different.	

[18] [redacted]

[redacted]

Ref. Doc.	Date	Content	Remark
		Finally, the Claimant stated that it expected a reply in 10 days.	
8	18/09/2015	The Consortium Representative confirmed to the Claimant, with data owners in copy, that the lead registrants of the substances listed in the Ref. Doc. 7 sell LoA to the joint registrations "*according to the cost sharing principles for the categories which [Consortium] have described several times*". The Consortium Representative pointed out that he "*cannot speak on behalf of the data owners*" regarding "*data sharing outside the scope of the [Consortium] model for whatever purpose. This a matter for each data owner to decide […]. However, in the context of the sharing of studies for potential joint registration of substances already registered by [Consortium] members, [the Consortium Representative] doubt whether [the Claimant] would get any response which differs from those that [the Claimant] have received recently*". The Consortium Representative further stated that the Consortium believes that "*the cost sharing model that [the Consortium] have proposed to [the Claimant] is non-discriminatory, fair and transparent and is an efficient, cost effective and pragmatic way sharing great deal of data between many related substances*". The Consortium Representative added that "*the use of category approach has allowed animal testing to be avoided*" and continued by stating that "*[t]he dossier and LoA costs for all the substances registered by [the Consortium] are reviewed regularly to take into account new registrants and [the Consortium] have a reimbursement mechanism in place for those registrants who have paid too much*". The Consortium Representative shared Claimants wish "*to avoid lengthy and fruitless negotiations*" and invited the Claimant to come back to the Consortium Representative if the Claimant wished to join any joint registrations. In addition, the Consortium Representative offered to the Claimant a possibility to discuss about the Claimant's registration objectives by phone.	
9	23/09/2015	The Claimant replied that it could not consider Consortium Representative's answer conclusive so it asked to be put into contact with Data Owners of the eight substances listed in Ref. Doc. 7. Claimant also refused the phone call because it preferred all interaction to be in writing "*for obvious reasons*".	
10	23/09/2015	The Consortium Representative informed the Claimant that he had forwarded Claimant's request "*to the data owners of the* [redacted]".	
11	05/10/2015	The Consortium Representative informed the Claimant that the LoA costs of substances registered by the	Only provided

[redacted]

Ref. Doc.	Date	Content	Remark
		Consortium had been recalculated taking into account the new co-registrant who had joined between November 2014 and August 2015. Consequently LoA costs for the substances of interest to the Claimant had decreased. The Consortium Representative further stated that he hopes that this helps Claimant's planning.	by the Other Party
12	06/10/2015	The Claimant informed the Consortium Representative that it had not been contacted by any of the Data Owners for the substances listed in the Ref. Doc. 7. The Claimant asked for their contacts so that it could proceed.	
13	06/10/2015	The Consortium Representative informed the Claimant that he copied Claimant's note to the concerned Data Owners and he hoped that Claimant hears from them soon.	
14	22/10/2015	The Claimant informed the Consortium Representative that most of Data Owners of the substances listed in the Ref. Doc. 7. had answered to the Claimant. Based on the replies, the Claimant had come to a conclusion that the Data Owners of all substances concerned offer data at the same total study cost mentioned in the cost breakdown dated 27/10/2014. The Claimant repeated its statement from the Ref. Doc. 7 that the used cost calculation model gives them two options, namely to pay a generic fee or to accept to pay whole cost of the study before repartition, and the Claimant considers these options not transparent and not fair, respectively. The Claimant further stated that it fels that its "*requests remain not satisfied*" and it had " *decided to appeal ECHA for application of article 30*." The Claimant added that as "*[r]equested by REACH, [the Consortium Representative] have fifteen days to eventually reply*." The Claimant stressed that it shared Consortium's "*concern for animal welfare and category approach at this regard*". The Claimant pointed out, however, that the "*Read Across approach should be aimed to maximize the [h]euristic value of a limited set of available data and minimize the cost of the dossier*". The Claimant further shared its impression that "*the way the category approach has been applied by [the Consortium] was conditioned by other considerations*". The Claimant brought up as an example that "*the same studies for endpoints* [redacted] *of the substances [listed in Ref. Doc. 7] have been used at least in 25 Dossiers and charged* [redacted] *each time*" and this would mean that "*the total cost of each study should be at least* [redacted]".	

[redacted]

Ref. Doc.	Date	Content	Remark
15	23/10/2015	The Consortium Representative promised to "*discuss [Claimant's] proposed appeal to ECHA with data owners concerned*" and asked if Claimant had contacted them individually. The Consortium Representative continued by explaining certain issues raised by the Claimant in the Ref. Doc. 14 concerning the Consortium's data sharing model: • "*Together with a desire to minimise testing on animals*", the objective of the Consortium's data sharing model is "*to maximise the [h]euristic value of a limited set of available data and minimise the cost of the dossier*". • The category approach applied by the Consortium is not conditioned by any other considerations than the ones mentioned in the in the first point above. • Same studies have been referred to in multiple dossiers but charged only once. The cost sharing model allows sharing the study costs "*across all the substances in a group where the study is used […] between numerous registrations*" leading to cost for every registration being minimised. The Consortium Representative repeated offer to discuss the model by phone "*with screen sharing*". The Consortium Representative continued by further explaining the used cost sharing model by stating that "*data owners have offered data to members of the Consortium for use in [Consortium] dossiers. Each study is given a value and this value is used in the cost sharing model for each subgroup*". Values of the studies specified in the Ref. Doc. 14 as example are based on "*Klimisch Reliability 2 (suitable as a key study)*" and Fleischer list price x [redacted] "*Since [Consortium's] cost sharing model applies across all the substances in the group/category, the value of [study] is shared between all the registrations in the group at the relevant tonnage band. Since all the data for all the substances in the category/group supports the category approach, all the studies are considered together as a group according to their applicable annex and the total cost divided between all registrants (according to the tonnage of the registration)*". Finally, the Consortium Representative stated that "*[Consortium] believe(s) that the category approach and the [Consortium] cost sharing model offer a low cost, robust and business-like way of sharing studies across a group of related substances and that the present arrangements […] allows read-across from a much wider pool of vertebrate animal and non-vertebrate animal testing data than would be available if a strictly one substance approach had been adopted.*"	
16	27/10/2015	The Claimant informed the Consortium Representative that data owners have replied to them but the replies had not added anything substantial but in any case the Claimant will send copies of these emails to	

[redacted]

Ref. Doc.	Date	Content	Remark
		the Consortium Representative. Claimant pointed out that it preferred only interactions in documentable written form. The Claimant further stated that "*there is no more substantial unclear point in [Consortium] Data Sharing Model*". The Claimant continued by arguing that the model is "*in full conflict with one of fairness basic principle of data sharing, that is to say 'SIEF members cannot be forced to pay for data and information they do not require' (See for instance CEFIC 'FAIR AND TRANSPARENT COST SHARING IN SIEFs' 05 December 2013 (first edition.)".* The Claimant also considered the calculation system unfair "*as it does not contain any fair provision to allow a potential co-registrant to opt-out certain studies if not under the unfair condition (as emerged by correspondence with Data Owners) of paying 100% of the cost of non opted out studies, where there are several other registrants and the cost of such non opted out studies could be equally shared by all*". The Claimant further stated that "*the calculation system remain[s] not transparent as it requests the payment of a generic fee for the data contained in the joint registration dossier, without […] detailed information on the costs of the individual studies for the single co-registrant*". The Claimant stated that it fully shared *"with [Consortium] the Read Across approach in order to minimize testing on animals*" but it disagreed on "*the way the accountancy side of data sharing has been managed*". Finally, the Claimant stated that it felt its requests remained not satisfied and repeated its intention to turn to ECHA "*for application of article 30 within prescribed terms*".	
17	28/10/2015	The Consortium Representative informed the Claimant that he had spoken to a number of the data owners who generally remained unsure of what the Claimant wanted. The Consortium Representative also stated that lead registrants and data owners were copied into correspondence between the Claimant and the Consortium Representative and wondered if Claimant's recent questions to data owners were unclear. The Consortium Representative assured that "*[a]ll the data owners will be happy to answer any specific, clear and direct questions*" regarding the studies they own. In response to the Claimant's statement that the cost sharing model of the Consortium is "*in full conflict with one of fairness basic principle of data sharing",* the Consortium Representative explained that their cost sharing model recognized that a registrant should not pay for costs related to a higher tier dossier. *As a consequence co-registrants only share in the cost of data related to the Annex at which they are*	

[redacted]

Ref. Doc.	Date	Content	Remark
		registering. This will include the studies directly summarized in their dossier and studies which may not be entered as study summaries but which are nevertheless summarized and referenced in the category justification. Since the category justification is dependent upon all the studies, it is right and proper that all registrants who rely on the justification should share the costs of the studies. Thus the Consortium disagreed that SIEF members are required to pay for unrequired data. Registrants with lower tonnage band paid less technical and administration costs. The Consortium Representative argued that it considered this cost distribution fair. In response to the Claimant's statement that the cost sharing model of the Consortium *"does not contain any fair provision to allow a potential co-registrant to opt-out certain studies",* the Consortium Representative pointed out that although the Claimant had stated many times that it considered opting-out it had not indicated "*what studies [Claimant] object to or what part of dossier [Claimant] would like to opt-out of*" so the Consortium Representative could not think how to work with the Claimant to meet its objective and welcomed the feedback from the Claimant in this matter. The Consortium Representative also stated that strength of the dossiers would reduce if studies were left out. The Consortium Representative asked if the Claimant has studies that might benefit individual registrations or the whole group. The Consortium Representative informed that if potential co-registrant has a right to refer to some studies the Consortium Representative has calculated "*a discount from the normal LoA price based on Consortium study value and the number of registrant sharing the cost*". The Consortium Representative added that the LoA price for individual studies was up to individual study owners and the Consortium Representative urged the Claimant to tell data owners what study it was interested in and for what purpose. In response to the Claimant's statement that *"the calculation system remain[s] not transparent as it requests the payment of a generic fee"*, the Consortium Representative stressed that the Consortium would not agree that "*the cost share amounts to a 'generic fee' as it has as its basis a defined set of studies with defined values*" and that cost sharing has been equal for Consortium members and non-members. The Consortium Representative repeated offer to demonstrate this by phone with screen sharing. In response to the Claimant's statement on its disagreement on "*the way the accountancy side of data sharing has been managed",* the Consortium Representative invited the Claimant to come up with	

[redacted]

Ref. Doc.	Date	Content	Remark
		alternative proposals that would be "*measured to maintain fairness*" to the over 130 co-registrants. In response to the Claimant's statement that it felt that its requests remained not satisfied and that it intended to turn to ECHA "*for application of article 30 within prescribed terms*", the Consortium Representative stated that they believed that the current offer from Consortium members was "*fair, non-discriminatory, transparent and above all business-like*". He pointed out that in case ECHA would grant to the Claimant right to refer, it would give to the Claimant access to "*a very small fraction of the studies that [the Claimant] will require to support [Claimant's] dossiers*". The Consortium Representative further indicated that gathering an opt-out dossier could be pricier than the offer to join the full joint registrations which has been made by [the Consortium Representative and by the lead registrants. The Consortium Representative counted that he had spent over 35 h replying to the Claimant's queries during the current year and he considered it as demonstration of Consortium members' commitment to reaching "*a satisfactory conclusion*".	
18	29/10/2015	The Claimant replied to the email of the Consortium Representative dated 28/10/2015 (Ref. Doc. 17) with six Data Owners [redacted] in copy. The content of the attachment of the email was the same as in the Ref. Doc. 7. In response to the Consortium Representative's statement that the data owners have generally remained unsure of what the Claimant wanted, the Claimant stated that "*[f]rankly speaking such dilatory / obstructive behaviour, after more than one year is embarrassing*". The Claimant continued by stating that tit would re-send a similar communication that it had sent to the data owners of the substance with CAS number [redacted] (Ref. Doc. 7) to the data owners of the substances listed in the Ref. Doc. 7. The Claimant further stated that as the Consortium Representative had spontaneously taken duty to contact data owners listed in Ref. Doc. 7, the Claimant could contact only five Data Owners [redacted] who had replied. The Claimant asked the Consortium Representative to forward the Claimant's mail to missing data owners and Lead Registrants within one week. In response to the Consortium Representative's statement that the Consortium would not agree that SIEF members are required to pay for unrequired data, the Claimant stated that "*[t]he technical strategy used […] is a free choi[c]e but [it] must be in compliance with the basic rules of data sharing established by REACH*". The Claimant continued by stating that REACH does not prescribe "*cost sharing of studies included*	Attachment provided only by the Other Party

[redacted]

Ref. Doc.	Date	Content	Remark
		in the 'category justification document'", while it clearly states the principle that "*SIEF members cannot be forced to pay for data and information they do not require*". The Claimant further argued that the Consortium Representative's justifications base on "*arbitrary assumption [that] there is no technical alternative to the category justification prepared by [the Consortium / the Consortium Representative]*". The Claimant pointed out that "*OECD working team on [a group of substances] has excluded [a particular group of substances] from the [group of substances] while [the Consortium / the Consortium Representative] has included them*" and "*multiple technical choices are available to a co-registrant to support a category justification*." In response to the Consortium Representative's statement that the LoA price for individual studies was up to individual study owners, the Claimant stated that that it had "*never requested a LOA to individual studies*" but instead it had kept requesting "*individual proportion of the cost of each study to be informed in the context of a potential […]co-registration, as prescribed by REACH*" since August 2014. The Claimant continued by stating that the "*[l]ead registrants or their legitimate representative should have supplied this information by default since the beginning*". Furthermore, the Claimant stated that it involved Data Owners [to negotiations] because the Consortium Representative claimed that the Data Owners were "*subjects entitled to communicate the individual proportions of the cost of each study*". The Claimant quoted REACH Article 11(3) points a) and c) which states "*A registrant may submit the information referred to in Article10(a)(iv), (vi), (vii) or (ix) separately if:* *a) it would be disproportionately costly for him to submit this information jointly; or*" "*c) he disagrees with the lead registrant on the selection of this information*". The Claimant also argued that its opting out decisions could be legitimately taken "*only after getting the requested info and after a comparison process (regarding quality of info and cost)*". The Claimant continued by stating that "*opting out decision taken 'a priori' without a comparison process and only on the base of data ownership / availability would be not legal according to REACH*". Finally, the Claimant repeated its request to receive cost of studies for "*single co-registrant (individual proportion)*" from "*whichever legitimately involved Party*". The Claimant further referred to ECHA Guidance on Data Sharing chapter 4.7.5 step 5 which states that "*sharing of data could be considered as not transparent, if the data owner requests the payment of a generic fee for the data contained in the joint registration dossier, without providing detailed information on*	

[redacted]

Ref. Doc.	Date	Content	Remark
		the costs of the individual studies". In response to the Consortium Representative's statement that the Consortium would not agree that "*the cost share amounts to a 'generic fee'*, the Claimant stated that it did "*respect [Consoritum's] free choices*" but that the Consortium had not till that moment provided "*detailed information on the costs of the individual studies*". In response to the Consortium Representative's invitation to come up with alternative proposals, the Claimant stated that "*it [is] responsibility of Lead Registrant or of his legitimate representative to make proposals in line with the principles of non discrimination, fairness and transparency*" and that the Claimant was "*available to accept whichever proposals in line with such principles*". Finally, the Claimant informed about its intention to turn to ECHA "*for application of article 30 within the term of 15 days since the date of this communication + 1 week*".	
19	29/10/2015	The Consortium Representative acknowledged the receipt of Ref.Doc. 18 and told that he had forwarded the Ref. Doc. 18 to the owners of the studies for eight[19] substances listed in the Ref. Doc. 18. The Consortium Representative informed as well that he remains available to discuss any counterproposal from the Claimant which "*might move [the Claimant and the Consortium Representative] towards a satisfactory conclusion on this matter*".	
20	09/11/2015	The Consortium Representative informed the Claimant that he had passed the Claimant's request to the Study Owners but he was unsure "*that they will be able to provide the information that [the Claimant] [had] requested of them*". The Claimant also argued that study owners were involved due to the parties' correspondence from September 2014 to April 2015 "*where the nature of [the Claimant's] request was indeed confusing and [the Claimant's] intentions were not clear since at the time [the Claimant] had not pre-registered 6 of the 9 substances and was giving mixed messages in [their] communication*". The Consortium Representative stated that "*[i]t is clear to him that in the context of the Claimant becoming part of the joint registration for the substances [listed], the study owners may not be able to answer [the Claimant's] request. But this will depend upon which studies [the Claimant] chose to refer to and how [the*	

[19] The table in the Ref. Doc. 18 lists nine substances, but one of the substances is dealt under a different category.

[redacted]

Ref. Doc.	Date	Content	Remark
		Claimant] propose to use them. Consequently [the Consortium Representative] do not expect that involvement of the study owners will achieve very much at this point in time". The Consortium Representative then explained that Lead Registrants and Consortium Management are responsible for cost sharing in the context of the existing join registration. In addition, the Consortium Representative stated that the Consortium understands that the Claimant rejects the cost sharing model that "*all other registrants*" had agreed upon. The Consortium Representative continued by stating that he understands that the Claimant might wish to "*exercise its right to opt out of certain parts of the dossiers*" but "*[i]n the context of a technical dossier which has been submitted as part of a category, the nature of the studies that [the Claimant] may wish to opt out of may have consequences for the overall integrity of [the Claimant's] dossier*". Finally, the Consortium Representative agreed that category approach is not the only approach open for the Claimant. The Consortium Representative pointed out that so far the Claimant had not indicated that "*the overall cost of LOA to the join submission or cost share for the information to support registration at each Annex*" would be "*disproportionally costly*" and the Claimant had not objected "*category approach as a strategy*" or "*inclusion of any study for scientific reasons*". Rather, the Claimant had supported read-across strategy giving alternatives to vertebrate animal testing. The Consortium Representative suggested two approaches for the Claimant to achieve its aims: Top down: The Claimant will pull out studies that the Claimant "*may object to*" from the Consortium cost sharing model. The Consortium had given discount to LoA to co-registrants for studies that it was inappropriate for them to pay for and this was done in such way that "*scientific integrity of the category justification was not affected*". Substantial changes would undermine "s*cientific justification for the strategy*" and alternative model would be needed as it would be unfair for the Claimant "*to rely on information that it was not prepared to share the cost of*". Bottom up: If the Claimant "*fundamentally object to the category approach adopted*", the Claimant may prefer constructing own opt-out dossier. The dossier would still "*be submitted as part of the joint registration but would not refer to any of the information and technical justification included in the current lead registration*". This new cost sharing model would need to be "fair, transparent and above all non-discriminatory" for the Claimant, existing Co-Registrants and Study Owners. The model would depend on	

[redacted]

Ref. Doc.	Date	Content	Remark
		terms upon which the Claimant wished to have access to the studies. The Consortium Representative invited the Claimant to reply to him if the Claimant wished to discuss "*opt out preferences*".	
21	14/12/2015	The Claimant informed the Consortium Representative that "*time limit for appealing ECHA for application of article 30*" was due and it had not received requested information. Therefore the Claimant was going to start "*the concerned procedure*".	
22	14/12/2015	The Consortium Representative acknowledged the receipt of the Ref. Doc. 21 and regretted that the parties could not discuss further as the Consortium Representative had proposed in Ref. Doc. 20.	
CORRESPONDENCE BETWEEN CLAIMANT AND DATA OWNER [redacted] CONCERNING THE SUBSTANCE WITH EC NUMBER [redacted]			
23	29/07/2015	The Data Owner informed the Claimant that the Data Owner had given to the Consortium studies on the Substance and on read across substances used in the dossier. The Data Owner also informed that [redacted] *of the Fleischer value was compensated for use of these studies for REACH purposes*". Furthermore, the Data Owner stated that it had commissioned a new study on read across substance and received [redacted] of its actual cost in line with "*rules of the consortium*". The Data Owner further attached "*details of the relevant end points, if the study was on [the substance on its own] or a read across substance used as part of the category and the compensation value of the study*". Finally, the Data Owner invited the Claimant to inform if the Claimant had other queries.	Attachment not provided
24	04/08/2015	The Claimant replied to the Data Owner that the Claimant had requested the Consortium Representative for "*proof of the study costs for the single registrant*". The Claimant stated that it "*already knew the total cost of each study*" and it needed "*to know the cost to access the study for the single registrant*". The Claimant remained waiting to hear from the Data Owner.	
25	07/08/2015	In order to "*find a fair solution*" the Data Owner asked how the Claimant wanted to "*use the data correctly*" and which end the Claimant wished to achieve. 1) Did the Claimant wish to join the joint submission? 2) Was the Claimant looking to buy data separately or just wanted full understanding of costs?	

[redacted]

Ref. Doc.	Date	Content	Remark
		3) Did the Claimant look to opt out of certain data?	
26	04/09/2015	The Claimant replied to the Ref. Doc. 25 with the Consortium Representative and the lead registrant in copy. The Claimant stated that its expectations had not been satisfied. The Claimant further clarified that 1. It was interested in joint registration for the Substance. 2. It had enquired the Consortium Representative about joint registration costs. 3. It had received SIEF agreement from the lead registrant of the substance. 4. "*SIEF agreement requested the payment of a generic fee for the data contained in the joint registration dossier without providing detailed information on the costs of the individual studies*", while the Claimant had repeatedly asked the Consortium Representative for "*joint registration proposal, explicating the identity and the cost of each study for the potential co-registrant, as clearly prescribed by REACh Regulation*". 5. According to the Consortium Representative, lead registrant was informed of dispute but "*never expressed his position on the matter*". 6. The Consortium Representative actually identified studies and gave cost breakdown with total cost of each study and LoA for different annexes. Cost of "*each study for the potential co-registrant has never been explicated*". The Consortium Representative had also claimed "*they were not authorized to review the terms of the SIEF agreement*" and directed the Claimant to "*data owners in order to obtain information about the cost of each study for the potential co-registrant*". 7. The Claimant had filed a dispute with ECHA. ECHA advised the Claimant to contact data owners for the requested information. 8. The Claimant wanted to know which is the cost of the Claimant's share of each study owned by the Data Owner. 9. The Claimant pointed out that it was uninterested in 1. total cost of each study 2. generic LoA cost to each annex 10. If the Data Owner could not provide the requested information, the Claimant "*kindly requested to express the reason*". 11. The Claimant kindly asked a reply "*within 15 days since the receipt of the present letter*".	

Ref. Doc.	Date	Content	Remark
CORRESPONDENCE BETWEEN CLAIMANT AND DATA OWNER [redacted]			
27	06/08/2015	The Data Owner informed the Claimant, with the Consortium Representative in copy, that "*[the Data Owner] owns data related to endpoint* [redacted]*'* ([redacted]*)*" included in the registration dossier of the substance with the EC number [redacted]	
28	04/09/2015	The Claimant replied to the Data Owner with reference to the Ref. Doc. 27. The message had the same content and same persons in copy as in Ref. Doc. 26.	
29	15/09/2015	The Data Owner informed the Claimant that it appreciated the Claimant's clarification in Ref. Doc. 28. The Data Owner stated that in context of joint registration of the Substance it offered access to their studies according to the cost sharing model adopted by the members of the Consortium. The Data Owner further stated that the Lead Registrant could provide SIEF agreement for the dossier and the Consortium Representative the current LoA costs. The Data Owner then advised the Claimant to contact the Lead Registrant and the Consortium Representative for further questions.	
30	09/10/2015	The Data Owner referred to Ref. Doc.'s 7 and 9, with the Consortium Representative and four Data Owners for the substances listed in the Ref. Doc. 7, in copy. The Data Owner offered access to its studies of the listed substances for joint registration based on Consortium's cost sharing methodology.	
CORRESPONDENCE BETWEEN CLAIMANT AND DATA OWNER [redacted] CONCERNING THE SUBSTANCE WITH EC NUMBER [redacted]			
31	03/08/2015	The Data Owner stated to the Claimant that it understood that the Claimant had received "*data matrix (studies/ valuation)*" from the Consortium Representative and the Data Owner asked what studies the Claimant was requesting access to.	
32	04/08/2015	The Claimant informed the Data Owner that it needed "*to know cost, for the single registrant, for access to all the studies used to prepare dossier*".	
33	04/08/2015	The Data Owner asked, with the Consortium Representative in copy, for which annex the Claimant required	

Ref. Doc.	Date	Content	Remark
		the studies. The Data Owner also stated that costs vary by tonnage band and it offered to sell an individual LoA at [redacted] of Fleischer.	
34	05/08/2015	The Claimant asked the Data Owner to send the list of studies that the Data Owner owns.	
35	05/08/2015	The Data Owner stated that it was happy to give a list of its studies for the annex that the Claimant was "*interested in (and entitled to)*". The Data Owner further indicated that it wished "*not to divulge more information than is absolutely necessary*" for the Claimant "*to fulfill REACH obligations*" and thus asked for which REACH annex the Claimant needed the studies.	
36	06/08/2015	The Claimant replied to the Data Owner that it was interested in tonnage band [redacted].	
37	04/09/2015	The Claimant replied to the Data Owner with reference to the Ref. Doc. 35. The message had the same content and same persons in copy as the Ref. Doc. 26.	
38	14/09/2015	The Data Owner informed the Claimant that it appreciated the Claimant's clarification in Ref. Doc. 37. The message had the same content as the Ref. Doc. 29. In addition, the Data Owner referred to the cost calculation for different tonnage bands presented in Ref. Doc. 33.	Only provided by the Data Owner
CORRESPONDENCE BETWEEN CLAIMANT AND DATA OWNER [redacted] CONCERNING THE SUBSTANCE WITH EC NUMBER [redacted]			
39	06/08/2015	The Data Owner informed the Claimant that it had provided the Consortium with results for [redacted] [redacted]y and [redacted] at value of the Fleischer price. The data owner asked the Claimant if this answered its question.	
40	04/09/2015	The Claimant replied to the Data Owner with reference to the Ref. Doc. 39. The message had the same content and same persons in copy as the Ref. Doc. 26.	
41	14/09/2015	The Data Owner informed the Claimant that it appreciated the Claimant's clarification in Ref. Doc. 40. The message had the same content as the Ref. Doc. 29	
CORRESPONDENCE BETWEEN CLAIMANT AND DATA OWNER [redacted]			
42	20/08/2015	The Data Owner asked the Claimant, with the Lead Registrant and the Consortium Representative in copy,	

Ref. Doc.	Date	Content	Remark
		for the Claimant's exact data needs for the substance with EC number [redacted]	
43	04/09/2015	The Claimant replied to the Data Owner with reference to the Ref. Doc. 42. The message had the same content and same persons in copy as the Ref. Doc. 26.	
44	08/10/2015	The Data Owner referred to Ref. Doc.'s 7 and 9, with the Consortium Representative and nine Data Owners for the substances listed in the Ref. Doc. 7, in copy. The message had the same content as the Ref. Doc. 30. In addition, the Data Owner offered to discuss with the Claimant about the right to refer to the Data Owener's studies for other purposes "*depending upon which study and how it is to be used*".	
CORRESPONDENCE BETWEEN CLAIMANT AND DATA OWNER [redacted] CONCERNING THE SUBSTANCE WITH EC NUMBER [redacted]			
45	25/08/2015	The Data Owner supplied the Claimant with its contact details.	
46	04/09/2015	The Claimant replied to the Data Owner with reference to the Ref. Doc. 45. The message had the same content and same persons in copy as the Ref. Doc. 26.	
47	23/10/2015	The Data Owner advised the Claimant to contact the Consortium Representative for all its questions.	
CORRESPONDENCE BETWEEN CLAIMANT AND DATA OWNER [redacted] CONCERNING THE SUBSTANCE WITH EC NUMBER [redacted]			
48	06/08/2015	The Data Owner provided the Claimant with cost details for studies it owned in an attachment. The Data Owner pointed out that: 1. "t*he right of use the studies is limited for the sole purpose of compliance with REACH requirements*" for the Substance. EC [redacted] The [redacted] of Fleischer value was calculated. The Claimant would be given "*copy of the robust study summaries of the studies*" and 2. right to sub-license to "*EU Affiliates or to Only Representatives of non EU-Affiliates. It is understood that a sub-license to Only Representatives can only be for the benefit of the non EU-Affiliates represented*". The Data Owner calculated "[redacted] *of the Fleischer value for REACH only and* [redacted] *of this value as [Data Owner] has registered only*". 3. for the internal work the Data Owner calculated an additional fee of [redacted]	Data sharing agreement and only provided by the Data Owner

[redacted]

Ref. Doc.	Date	Content	Remark
		Finally, the Data Owner stated that if the Claimant agreed, it should fill and sign the attached data sharing agreement.	
49	04/09/2015	The Claimant replied to the Data Owner with reference to the Ref. Doc. 48. The message had the same content and same persons in copy as the Ref. Doc. 26.	
50	10/09/2015	The Data acknowledged the receipt of the Ref. Doc. 49. "*For the sake of completeness*", the Data Owner provided the substance identification profile of the Substance. The Data Owner offered access to its studies according to cost sharing model adopted by the Consortium. The Data Owner also pointed out that REACH requires only sharing of vertebrate animal studies. The Data Owner continued by pointing out that "*[t]he cost allocation and sharing are based on rules which ensure fairness and transparency*" and by regretting that category cost sharing model is more complicated than it would be in the case of a single substance but the Data Owner considered it "*appropriate given the way […] the […] category dossiers have been constructed*". The Data Owner pointed out that "*the cost calculation model does not allow for the simple allocation of costs per study per dossier since costs have been calculated at the category level*" and for that reason "*the Consortium Management has been unable to provide the information that [the Claimant] have repeatedly asked for*". Furthermore, the Data Owner stated that for the sake of maintaining fairness and a consistent approach in the context of a joint registration, "*the cost sharing model which has been so widely accepted*" cannot be changed and the Data Owner recommended the Claimant to accept the model "*as it is*". The Data Owner explained that "*[i]n the past, it has occurred that certain co-registrants already had the legal right to refer to studies which were already referenced in a dossier (or in the category)*". The Data Owner continued stating that "*[i]n such circumstances it would be inappropriate for them to be asked to pay again*" and "*[i]n these cases, the Consortium Management calculated a discount based on the cost share for the individual study for one registrant*". The Data Owner further explained that "*[i]n the […] category, the cost for a study for an Annex VIII endpoint is shared between 123 registrants and hence the individual cost share is 1/123rd of the study value*" but "*[t]he cost share for Annex IX is different*". The Data Owner then stressed that elimination or substitution of studies "*would require changes to the lead dossier and come at additional cost*".	Only provided by the Data Owner

[redacted]

Ref. Doc.	Date	Content	Remark
		The Data Owner then provided the current LoA price, but noted that recalculation would shortly slightly decrease the price. The Data Owner also offered discount if the Claimant had legitimate right to refer to studies already in the dossier and attached data matrix for the Substance including a column "*Discount applied to LOA price for those co-registrants already having legitimate access to the same study*". The Data Owner further pointed out that "*[i]f [the Claimant] wish to opt out of certain endpoints and substitute new data, then there might be additional costs as the requirement for registrants to refer to the same dossier would necessitate an update of the lead dossier*". The Data Owner finally invited the Claimant to get back to them if the Claimant wished to procure access to its studies for any other purposes that registration of the Substances.	
CORRESPONDENCE BETWEEN CLAIMANT AND DATA OWNER [redacted]			
51	17/08/2015	The Data Owner apologised the Claimant for the late reply, asked how it could help the Claimant and requested more specifications.	
52	04/09/2015	The Claimant replied to the Data Owner with reference to the Ref. Doc. 51. The message had the same content and same persons in copy as Ref. Doc. 26.	
53	15/09/2015	The Data Owner advised that the study it owned was used for read-across in the registration dossier of the substance with EC number [redacted]. The Data Owner further asked whether the Claimant was still interested in referring to the study.	
54	15/09/2015	The Claimant confirmed its interest in referring to the study.	
55	16/09/2015	The Data Owner referred to the Claimant's request for the cost of access to studies belonging to the Data Owner for use in the registration of the substance with EC number [redacted]. The message had the same content as the Ref. Doc. 29. The Data Owner also made a quotation for the LoA for its individual study in case the Claimant preferred to opt out. The Data Owner then invited the Claimant to contact the Lead Registrant and the Consortium Representative concerning joining the joint submission and to contact themselves concerning additional	

[redacted]

Ref. Doc.	Date	Content	Remark
		information of LoA costs of its individual study.	
56	07/10/2015	The Data Owner referred to Ref. Doc.'s 7 and 9 with the Consortium Representative in copy. The message had the same content as the Ref. Doc. 30 although the Data Owner informed that it did not own any study for the seven substances subject to the Claimant's request.	
CORRESPONDENCE BETWEEN CLAIMANT AND DATA OWNER [redacted]			
57	08/10/2015	The Data Owner referred to Ref. Doc.'s 7 and 9, with the Consortium Representative and five Data Owners for the substances listed in the Ref. Doc. 7, in copy. The message had the same content as the Ref. Doc. 30.	
CORRESPONDENCE BETWEEN CLAIMANT AND DATA OWNER [redacted].			
58	09/10/2015	The Data Owner referred to Ref. Doc.'s 7 and 9, with the Consortium Representative and nine Data Owners for the substances listed in the Ref. Doc. 7, in copy. The message had the same content as the Ref. Doc. 30.	
59	04/11/2015	The Data Owner informed the Claimant, with the Consortium Representative in copy, that it was owner of study [redacted] for the substance with EC number [redacted]. This study had been shared with the Consortium to support the registrations of substances in the category. LoA to the joint registration for the substance was available from lead registrant for companies wishing to participate in joint registration with cost sharing according to the [redacted] The Data Owner also stated that all discussions concerning the cost sharing model for the joint registration should be directed to the lead registrants and to the Consortium Representative.	