[redacted]

Addressee (Claimant):

[redacted]

Sent via REACH-IT

Copy to Other Party:

[redacted]

Sent via REACH-IT

Reference number of the dispute claim	[redacted]
Decision number	[redacted]
Name of the substance disputed	[redacted]
EC number of the substance disputed	[redacted]

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

Dear [redacted],

On 23 June 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 requested the Other Party to also provide documentary evidence regarding the negotiations. The Other Party submitted the documentary evidence on 29 June 2016.

Based on the documentation supplied by both parties, ECHA has decided to grant you, as the Claimant, the permission to refer to the vertebrate animal studies requested from the Other Party for the above-mentioned substance.

The Other Party shall have a claim on you for an equal share of the cost, provided they make the full study report available to you, which shall be enforceable in the national courts according to Article 30(3) of REACH.

In accordance with Article 3(2) of the Commission Implementing Regulation (EU) 2016/9 on

joint submission of data and data sharing[1], ECHA also provides you with the token to the joint submission in order to ensure that your registration dossier will be part of the existing joint submission for the substance.

The permission to refer concerns the studies indicated in Annex I. The statement of reasons regarding the assessment of the data sharing dispute is set out in Annex II to this decision, while a tabular overview of the factual background regarding the data sharing negotiations is set out in Annex III. Instructions on how to prepare and submit your registration dossier after the resolution of the data sharing dispute procedure are provided in Annex IV. The endpoint study records for which permission to refer has been granted for the substance are provided in Annex V.

As a remark, ECHA reminds both parties that despite of the present decision they are still at liberty to reach a voluntary agreement. This would be in the parties' own interest, because they could enter into an agreement that reflects their needs, including, in particular, the sharing of non-vertebrate animal data, which is not covered by the permission to refer granted in the present decision. Accordingly, ECHA strongly encourages the parties to negotiate further in order to reach an agreement that will be satisfactory for both parties.

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 Schilliger-Musset
Director of Registration[2]

[1] 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.
[2] As this is an electronic document, it is not physically signed. This communication has been approved according to the ECHA's internal decision-approval process.

Annex I to decision [redacted]

LIST OF STUDIES SUBJECT TO THE DISPUTE, TO WHICH ECHA GRANTS THE PERMISSION TO REFER

Below ECHA has listed the studies involving vertebrate animal testing for which the Claimant has been granted a permission to refer. Studies that were subject to the negotiations but do not involve vertebrate animal testing are not covered by the permission to refer granted in this decision.

Endpoint	Title of the study
[redacted]	[redacted]
	[redacted]
	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
	[redacted]
	[redacted]
[redacted]	[redacted]
	[redacted]
[redacted]	[redacted]
	[redacted]
[redacted]	[redacted]
	[redacted]
[redacted]	[redacted]
	[redacted]
[redacted]	[redacted]
	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Annex II to decision [redacted]

STATEMENT OF REASONS REGARDING THE ASSESSMENT OF THE DATA SHARING DISPUTE

Article 30(1) of the REACH Regulation sets out as a pre-requisite that SIEF '*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 which have already been submitted to ECHA by another registrant, Article 30(3) of the REACH Regulation requires ECHA to determine whether to grant the claimant a permission to refer to the information contained in the registration dossier, i.e. to the relevant studies. 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, 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.

Making every effort to share the data and their related costs in a fair, transparent and non-discriminatory way means that existing registrants are required to provide to potential registrants upon request the itemisation and justification of all relevant costs to be shared, both data-related and administrative costs. This has been further reinforced in the Commission Implementing Regulation (EC) 2016/9 on joint submission of data and data sharing, which sets out criteria aimed to facilitate data sharing between existing and potential registrants, to help the potential registrant understand the data owner's cost calculation and thus enable them to engage in meaningful data sharing negotiations.

Making every effort requires the parties to negotiate the sharing of data and related costs as constructively as possible, to make sure that the negotiations move forward swiftly by expressing their arguments and concerns, and by replying to each other's questions and arguments. When the existing registrants see that the potential registrant needs to register urgently, they must take this into account, and not delay sending crucial information on the data and their costs.

Factual background

The Claimant initiated the negotiations on 12 June 2015[3] with a request for '*the latest LOA* [Letter of Access] *price for the registration with tonnage band* [redacted]*a'* for two substances. In their reply[4], the Other Party provided the LoA prices for three substances, including the substance titanium tetrabutanolate with EC no. [redacted] which is subject to the dispute at hand, for which a LoA price of [redacted] EUR for both [redacted] as well as [redacted] was quoted.

In the following exchanges[5], the Other Party clarified that the dossier did not include any testing proposals as the '*information […] available fulfilled the information requirements of*

[3] See reference no. 1
[4] See reference no. 2
[5] See references no. 3, 4, 5, 6, and 7

Annex IX' and informed that the quoted LoA prices *'are valid until May 2018 and will not be recalculated before that'*[6].

On 11 February 2016, the Claimant confirmed their intention to register the substance subject to this dispute at a tonnage band of [redacted] and with reference to the Commission Implementing Regulation (EC) 2016/9 requested an *'itemisation of costs and the reimbursement mechanism for LOA'*[7]. Subsequently, they also requested the Substance Identity Profile[8] and raised the urgency to receive the requested information[9].

The Other Party provided the Substance Identity Profile on 11 March 2016[10], and on 15 March 2016 sent a revised quote for the LoA of [redacted] EUR and broke down the cost into 'project costs', '*existing data'*, '*new data'*, '*articles'*, and '*read across'*, as well as '*substance specific third party costs'* and '*post project and processing costs*'[11].

In their reply, the Claimant stated that the '*itemized costs* [are] *not transparent and not understandable*'. They highlighted that the previously quoted LoA price was lower and was supposed to be '*valid until May 2018*', and requested the Other Party to '*explain* […] *the price difference*'. Further, they asked for a reimbursement mechanism in accordance with the Commission Implementing Regulation 2016/9 and in a follow-up message underlined again the urgency[12].

The Other Party explained that the price increase was caused by the need to review the '*applied costing principles'* as a consequence of the Commission Implementing Regulation, and that *'at the process the prices have changed'.* They informed that the costs were divided by the number of registrants, that the tonnage category was used '*as a weight in dividing the data cost'* and that the reimbursement mechanism was under discussion with the '*Leadership group*'[13].

On 6 May 2016, the Claimant replied that the '[i]*temisation of data should list the cost related to data according to* [redacted] *of REACh Regulation (for tonnage band* [redacted]*), administrative work and contain a justification*' and provided a table, in which the Other Party could justify each cost item. They again reminded of the obligation to have a reimbursement scheme in place and asked for the number of registrants.[14]

The Other Party provided the names of the endpoints covered under the items '*new data*', '*existing data*' and '*articles*', and referred to [redacted] *of REACH*' for all of them. They wrote that the '*share of data cost is determined by using different registrants data cost for the substance as a weight in dividing the total cost*.' They also wrote that the cost item '*Post project and Processing Costs*' meant '*consortia costs carried by the consortia members beyond the end of the LR registration project*.' They thereby considered to have addressed the Claimant's questions '*using best efforts*' and '*have now provided the*

[6] See reference no. 4
[7] See reference no. 8
[8] See reference no. 11
[9] See references no. 12 and 14
[10] See reference no. 15
[11] See reference no. 16
[12] See references no. 17 and 18
[13] See reference no. 19
[14] See reference no. 20

information available according to these legal requirement [of the Commission Implementing Regulation]'.[15]

In their reply of 26 May 2016[16], the Claimant provided price quotes from two different sources per study and endpoint for the costs listed under '*new data*' with a lower sum than the data owner had provided, and asked for a verification of the Other Party's costs. In addition, they stated that '*the study value may decrease if the right to refer is restricted for the REACH registration for purposes only*'. Regarding the number of registrants amongst which to share the costs, they sent a screenshot from ECHA's dissemination website listing six companies, and consequently asked to divide the total cost by seven to establish the individual share of the costs. Finally, they requested an explanation for the cost item '*Substance specific third party cost*', an itemisation of the '*project cost*' and again challenged the increase of the LoA price.

On 8 June 2016[17], the Other Party provided the cost per study for the '*new data'* as well as additional explanations for the more expensive tests for the endpoints listed by the Claimant. Further to that, they wrote that they considered that they were not required to justify costs that were '*incurred and paid long ago'* and that the '*costs are what they are*'. Regarding the number of registrants amongst which to share the cost, they claimed that there were '*currently 5 registrants*' and that '*weighted averages […] based on the data requirements for the tonnage*' were used to determine the individual contribution. Finally, they '*consider to have done* [their] *best effort*'.

Assessment

Hence the negotiations were blocked, because the Claimant and the Other Party could not agree on the value of the studies. In particular, the Claimant did not understand the Other Party's cost calculation and required more detailed cost information, which the Other Party refused to provide.

In order to agree on fair, transparent and non-discriminatory sharing of data and costs, the parties typically need to find a common understanding of the costs of the data. Communicating on the cost calculation is therefore a pre-requisite to data sharing negotiations. A potential registrant is entitled to receive upon request sufficiently detailed information to understand and assess the LoA price in order to establish if it is fair, transparent and non-discriminatory as required by Article 30(3) of the REACH Regulation. This has been confirmed by the Commission Implementing Regulation (EC) 2016/9, which clarifies that a potential registrant has the right to receive a meaningful cost breakdown (itemisation), *inter alia* linking cost items with data requirements and providing a justification for each cost item. The Implementing Regulation also aims at facilitating data sharing negotiations for new registrants, who are faced with existing registrants, who concluded data sharing agreements earlier. It does so amongst others by creating transparency regarding all the data to be shared. Article 2 of the Implementing Regulation therefore foresees an itemisation of all costs, past, present and future, in data sharing agreements. The information provided must be detailed enough to allow the potential registrant to assess the specific need for the studies,

[15] See reference no. 21
[16] See reference no. 22
[17] See reference no. 23

their individual cost and the relevance of administrative costs. In addition, it stipulates that a reimbursement mechanism shall be in place.

The Claimant made efforts to understand the LoA cost by requesting a cost breakdown[18] and by asking for further information related to individual cost items which they found unclear[19]. They also questioned the applied calculations, e.g. in relation to the number of registrants amongst which to share the total costs by reference to public information on ECHA's webpages[20], and requested to have a reimbursement mechanism in place[21]. They made further considerable efforts to understand the amounts quoted by the Other Party by providing their own price quotes for the item '*new data*' and comparing the sum to the Other Party's request[22]. They also consistently challenged the cost increase of the LoA and asked for a detailed explanation as disagreed with the Other Party's arguments[23].

The Other Party provided a first cost overview, which listed the sums for cost categories that were not explained and without going to the level of individual studies.[24] Upon repeated request by the Claimant, the Other Party provided an overview for the item '*new data*', where they listed the cost per endpoint and quoted the test guideline used[25]. No such information was made available for the other cost items. The other items of data cost were only generically linked to the annexes of the REACH Regulation, while the biggest cost item, the '*project cost*', was not explained at all.

This information however did not put the Claimant into a position to understand which studies they would buy access to, the studies' individual cost, whether they needed them and whether any administrative costs claimed were relevant to them. In particular the so-called project cost, which makes up by far the biggest proportion of the claimed cost, was not explained at all. Without knowing what they were asked to pay for, the Claimant was not in a position to engage in negotiations on data sharing.

Finally, when the Claimant requested more detailed information and justifications for certain disagreed or unclear matters, the Other Party stated '[t]*he costs are what they are*', '*Do not have further comments on this*' and that they '*consider to have done* [their] *best effort*'[26], thereby saying that they were not available for further discussions nor willing to provide more detailed information to enable the Claimant to assess the LoA price.

Concerning the reimbursement scheme, the Other Party claimed to have triggered discussions within the '*Leadership group*'[27]. However, by the time the dispute was lodged they had not presented a reimbursement scheme. In addition, when the Claimant pointed them to the six companies listed as registrants on ECHA's website[28], the Other Party merely claimed that

[18] See references no. 8, 10, 12, 17, 18, 20, and 22
[19] See references no. 3, 5, 17, 18, 20, and 22
[20] See references no. 20 and 22
[21] See references no. 8, 17, 20, and 22
[22] See reference no. 22
[23] See references no. 17, 18, 20, and 22
[24] See reference no. 16
[25] See references no. 21 and 23
[26] See reference no. 23
[27] See reference no. 19
[28] See reference no. 22

there were '*currently 5 registrants*' only but did not explain why their calculation did not take into account all registrants of the substance that were shown on the ECHA website[29].

Further, the Claimant informed the Other Party that they intended to register in the tonnage band [redacted][30]. Therefore, the Other Party knew that the Claimant was under an objective urgency to progress with their registration, as for volumes above [redacted] the registration is prerequisite for market access. In addition, the Claimant repeatedly highlighted that they were in an urgency to progress the negotiations[31]. Nevertheless, one year after the Claimant had initiated the discussions, the Other Party had not provided a cost breakdown that would allow the Claimant to understand how the LoA price was calculated nor provided a reimbursement scheme.

When the Other Party provided the first LoA price on 15 June 2015[32] only three days after the Claimant's request, the quoted price had to comply with the requirements of fair, transparent and non-discriminatory cost and data sharing. Consequently, an '*extremely high*'[33] increase of the LoA price – which was also in contradiction to their earlier statement that the price would be '*valid until May 2018*' – would have required the Other Party to provide an explanation that replies to the Claimant's questions regarding the increase in order to comply with the obligation to make every effort in the data sharing negotiations.

Conclusion

Based on the above, ECHA concludes that the Other Party did not make every effort to reach an agreement to share data.

The Other Party did not provide the Claimant with sufficient information to enable them to assess whether the LoA price is fair, transparent and non-discriminatory and refused to provide further information. Thereby, they effectively terminated the negotiations before the Claimant would have been in a position to assess if the LoA costs were fair, transparent and non-discriminatory. In addition, they failed to make every effort to provide a reimbursement scheme within a reasonable timeline that takes into account the objective urgency for the Claimant to register the substance. Finally, they failed to explain their proposal to share the costs by 6 instead of 7.

Against this background, the Claimant made every effort to find an agreement and filed the data sharing dispute as a measure of last resort.

Therefore, ECHA grants the Claimant permission to refer to certain data, submitted by the Other Party, listed in Annex I to the present decision.

[29] See reference no. 23
[30] See reference no. 5
[31] See references no. 11, 12 and 18
[32] See reference no. 2
[33] See reference no. 22

[redacted]

Annex III to decision [redacted]

TABULAR OVERVIEW OF THE FACTUAL BACKGROUND REGARDING THE DATA SHARING NEGOTIATIONS

Ref. No.	Date	Content	Remark
1	12/06/2015	The Claimant contacts the Other Party and asks about '*the latest LOA price for the registration with tonnage band* [redacted]' for the substance [redacted], *CAS no.:* [redacted] *EC no.:* [redacted]'. In addition, they ask whether the Other Party was '*Lead Registrant for the* [redacted], *CAS no.:* [redacted], *EC no.:* [redacted]'.	
2	15/06/2015	The Other Party provides the LoA prices for three substances: (1) [redacted]*), CAS no.:* [redacted], *EC no:* [redacted]': [redacted] EUR; (2) [redacted], *CAS no.:* [redacted], *EC no.:* [redacted] EUR (3) [redacted] *CAS no.:* [redacted], *EC no.:* [redacted]: [redacted] EUR These communicated prices are the same for both the [redacted] and [redacted]; the LoA for [redacted] '*is 50% of the full price*'.	
3	25/09/2015	The Claimant requests '*the current prices of the LoAs*' and asks '*[w]hich kind of and how many test proposals out of Annex IX, REACh Regulation have to be issued. Could you please call the endpoints?*' related to the three substances listed by the Other Party.	
4	05/10/2015	The Other Party informs that the LoA prices quoted previously '*are valid until May 2018 and will not be recalculated before that*'. Regarding the testing proposals, they inform that there are no testing proposals in the registrations as the '*information we had available fulfilled the information requirements of Annex IX*'.	
5	05/10/2015	The Claimant confirms their interest in a registration for the tonnage band [redacted]. Regarding the issue of testing proposals, they request clarification if *'all the endpoints by Annex IX of REACh Regulation [have] been covered or did [the Other Party] submit a testing proposal and wait for ECHA approval*'. They further ask if the LoA includes all Annex IX endpoints.	

Ref. No.	Date	Content	Remark
6	06/10/2015	The Other Party confirms that '*all endpoints [for Annex IX] are covered*'.	
7	06/10/2015	The Claimant thanks for the answer.	Only provided by the Other Party.
8	11/02/2016	The Claimant informs they '*intend the registration and purchase the LOAs for: titanium tetraisopropanolate, CAS no.:* [redacted] *and titanium tetrabutanolate CAS no.:* [redacted]*, tonnage band:* [redacted] *on April 2016*' and request the '*itemisation of costs and the reimbursement mechanism for LOA' with reference to the 'Commission Implementing Regulation 2016/9*'.	
9	12/02/2016	The Other Party informs they are '*in the process of itemization*' and promises to '*revert back to [the Claimant] with cost breakdown shortly*'.	
10	12/02/2016	The Claimant confirms receipt and asks to be kept informed.	
11	02/03/2016	The Claimant requests the Substance Identification Profile (SIP) for the two substances mentioned in their email of 11/02/2016.	
12	09/03/2016	The Claimant sends a reminder and states they '*need this information urgently*'.	
13	10/03/2016	The Other Party apologises for the delay, writing they '*need to itemize the costs of* [redacted] *at once*', and promises to send the cost breakdown on 14/03/2016.	
14	10/03/2016	The Claimant repeats their request for the SIP, highlighting again the urgency, and asks whether '[redacted] *[is] a monomer*'.	
15	11/03/2016	The Other Party confirms that titanium [redacted] is a monomer and attaches the SIPs. They further	Attachments (SIP) not

Ref. No.	Date	Content	Remark
		ask if the Claimant had not received the SIP by email of 03/03/016 already.	provided. Email of 03/03/2016 not provided by either party.
16	15/03/2016	The Other Party sends the '*itemized costs*' for the two substances in question, listing '*project costs*', '*existing data*', '*new data*', '*articles*', and '*read across*', as well as '*substance specific third party costs*' and '*post project and processing costs*'. They inform that the LoA prices for [redacted] are [redacted] EUR [redacted], CAS no.: [redacted]) and [redacted] EUR ([redacted], CAS no.: [redacted]). [redacted]	
17	15/03/2016	The Claimant states they find the '*itemized costs not transparent and not understandable*'. With reference to the Other Party's emails of 15/06/2015 and 05/10/2015, the Claimant points out that the LoA prices were	

Ref. No.	Date	Content	Remark
		lower [redacted] EUR and [redacted] EU respectively) and that they were supposed to be '*valid until May 2018'*. The Claimant requests to '*explain […] the price difference'* and asks for a reimbursement mechanism in accordance with the Commission Implementing Regulation 2016/9.	
18	17/03/2016	The Claimant asks for to receive an '*explanation about the price difference urgently'*.	Only provided by the Other Party.
19	18/03/2016	With reference to the Commission Implementing Regulation 2016/9, the Other Party informs that '*change in regulation has made us go through all of the applied costing principles – at the process the prices have changed'*. They further write that '*Project costs are divided by number of (current+1) registrants*' and that '*itemized data costs in the different categories are divided per substance. After that the registrant tonnage category (ie. data requirement) is used as a weight in dividing the data cost'*. In relation to reimbursement mechanism they inform that discussions with their '*Leadership group'* and lawyers are ongoing to '*implement the necessary contractual amendments*'.	
20	06/05/2016	The Claimant states that *'[i]temisation of data should list the cost related to data according to [redacted] of REACh Regulation (for tonnage band [redacted]), administrative work and contain a justification*.' On that basis, they pose specific questions regarding each of the cost items listed by the Other Party, and request a justification for each cost item. Further, they highlight that the '*cost-sharing model must include reimbursement mechanism*' and ask for '*the number of registrants'*. Finally, they request an answer '*not later than 17.05.2016*'.	
21	17/05/2016	The Other Party replies that they consider to have addressed the Claimant's questions '*using best efforts*' and '*have now provided the information available according to these legal requirement [of the Commission Implementing Regulation]'.* Further, they state that the Commission Implementing Regulation 2016/9 '*is not intended to have retroactive legal effect so as to require the previous registrants to provide the same level of information ante and post the entry into force'*. They write that *'Under [Article] 2(a) all relevant costs incurred after the date of entry into force are to be provided, under [Article] 2(b) proof of the cost of any study completed before the date of entry into force is to be provided and [Article] 2(c) make*	

[redacted]

Ref. No.	Date	Content	Remark
		every effort to provide itemization of all other relevant costs'. Therefore, they consider that they '*have now provided the information available according to these legal requirement*'. In addition, they provide the names of the endpoints under the items '*new data'*, '*existing data'*, and '*[published] articles'*, and refer to [redacted] *of REACH*' for all of them. Further, they point to ECHA's dissemination page '*to see the full references'*. For the item '*Share of Data Costs'*, they state that '*Data cost is divided into different tonnage bands depending on the requirement. The share of data cost is determined by using different registrants data cost for the substance as a weight in dividing the total cost*'. Regarding the item '*Post project and Processing Costs'*, they write that '[*t]his consists of consortia costs carried by the consortia members beyond the end of the LR registration project. The final figure will be adjusted at 2018 reimbursement time'*.	
22	26/05/2016	The Claimant poses to the Other Party further questions regarding cost overview. Regarding the item '*new data'*, they provide their own price quotes per study (based on '*IFRA(2010)'* and '*RTC(2015)*'):	

[redacted]

Ref. No.	Date	Content	Remark
		[redacted] On this basis, they calculate a total for this cost item which is lower than the cost quoted by the Other Party and ask the Other Party to provide the actual costs per study. Further, they state that *'the study value may decrease if the right to refer is restricted for the REACH registration for purposes only'*. With reference to ECHA's dissemination website, they point out that there are currently 6 registrants for the substance titanium tetraisopropanolate (CAS no. [redacted]; EC no. [redacted] and provide a screenshot supporting their statement:	

[redacted]

Ref. No.	Date	Content	Remark
		Registration: This substance has 6 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s). Please see Registrants/Suppliers details. **Registration data** open all close all  Hence, they ask to divide the costs by 7 and state that the total data costs should be '[redacted] *€ not* [redacted] *€ per registrant*'. Further, they request an explanation for the cost item '*Substance specific third party cost*' and an itemisation of the '*project cost*'. Regarding the latest price quotes, they write that the '*price increase of LoAs […] for period July 2015 to March 2016 are extremely high. […] [They] cannot believe that the corresponding prices have gone up by* [redacted] *€ and* [redacted] *€ per registrant*'.	
23	08/06/2016	Regarding the item '*new data*', the Other Party provides the cost per study as well as additional explanations for the more expensive tests. With a view to the regulatory requirement to provide an itemisation of the costs, they write that in their understanding this '*does not mean that a cost, already incurred and paid long ago, could be claimed to be erroneous by any third party. The costs in question has been incurred in order to fulfill the requirements for a Lead Registrant Dossier. The costs are what they are*'. Concerning the number of registrants amongst whom to share the costs, they write that '*There are currently 5 registrants – belonging to 2 different tonnage bands each with differing data costs*', and that the individual costs were calculated as '*weighted averages based on the data cost that a registrant should pay based on the data requirements for the tonnage*'. For the cost item '*Substance specific third party cost*', they state that this relates to data acquired from another Consortium and therefore is '*a cost [the Claimant] should pay*'.	

[redacted]

Ref. No.	Date	Content	Remark
		Finally, they write that '*the type and details of the itemization exercise will differ from case to case*' and that they '*consider to have done our best effort: [they] have provided proof of the cost of the studies and provided itemization of all other costs incurred*'.	