[redacted]

13 April 2016

Addressee (Claimant):

[redacted]

Sent via REACH-IT

Copy to Other Party:

[redacted]

represented by:

[redacted]

Sent via REACH-IT

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

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

Dear [redacted],

On 22 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). The claim has been registered at ECHA on 25 January 2016.

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 15 February 2016, as requested by ECHA.

[redacted]

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Based on the documentation supplied by both parties, ECHA has decided to grant you, as the Claimant, permission to refer to certain 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 has also decided to provide 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 the factual background regarding the data sharing negotiations is set out in Annex III. The endpoint study records for which permission to refer has been granted for the substance are provided in Annex IV. Instructions on how to prepare and submit your registration dossier after resolution of the data sharing dispute procedure 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. 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 Musset
Director of Registration

Annexes:

Annex I:	List of studies subject to the dispute, to which ECHA grants the permission to refer
Annex II:	Statement of reasons regarding the assessment of the data sharing dispute
Annex III:	Factual background regarding the data sharing negotiations
Annex IV:	Endpoint study records for which permission to refer has been granted for the substance
Annex V:	Instructions on how to prepare and submit your registration dossier after resolution of the data sharing dispute procedure

[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.

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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. The studies that do not involve vertebrate animal testing are not subject to the current 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]

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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 the parties 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 replying to each other's questions and arguments. In particular, 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 information can help the potential registrant to understand the basis of the cost calculation and thus allow it to conduct sensible data sharing negotiations. Parties are also required to maintain a cooperative approach and be a reliable partner in the negotiations, including by being ready to act in a swift manner while they must ensure that the chosen model of conducting the data sharing negotiations does not hinder their timely progress.

On 13 February 2015, the Claimant initiated contacts with the Other Party requesting information on the letter of access (LoA) to the joint submission for a registration between [redacted].[2] In its reply dated 23 March 2015,[3] the Other Party, referring to the costs for the registration of the substance set out in the SIEF agreement, as well as a pre-payment the Claimant had already made in relation to those costs, indicated that the LoA to the joint submission for a registration between [redacted] amounts to [redacted]. On 3 June 2015, the Claimant requested from the Other Party more detailed information on the cost structure set out in the SIEF agreement and, in particular, a breakdown of the amount of [redacted] corresponding to the costs for '*Lead Registrant (Consortium & Management Tasks, travel expenses 2007-2010'* (hereinafter referred to as 'the Lead Registrant's costs')[4]. In its reply dated 16 June 2015,[5] in relation to the requested breakdown of the Lead Registrant's costs, the Other Party indicated that '*Several experts*

[2] See reference no. 2. The Claimant and the Other Party were in data sharing negotiations between 2009 and 2012 - see reference no. 1. As a result of those negotiations the Claimant signed the SIEF agreement for the registration of the substance on 20 December 2010.
[3] See reference no. 5.
[4] See reference no. 6.
[5] See reference no. 7.

(chemists, toxicologists, etc), managers, lawyers and other experts of these companies were and are involved. Contracts had to be reviewed, bank accounts had to be opened, discussions on C&L issues, studies to be initiated, and, and, and.'. In addition, the Other Party referred the Claimant to an ECHA's Newsletter which included information on the costs of the management of the consortium for the joint application for authorisation for chromium trioxide.[6]

On 6 July and 13 October 2015, the Claimant repeated its request for a detailed breakdown of the Lead Registrant's costs claiming that the provided information was not sufficient to justify their '*disproportionately high*' nature.[7] On 3 December 2015, the Other Party indicated that '[a] *breakdown will be available after 2018 in the course of reimbursement calculation*'.[8] On 19 January 2016, and after several reminders[9] from the Claimant, the Other Party provided some further information stating that 87% of those costs referred to '*Personnel costs intern (REACH-Team, Product Safety), 2007 to 2010',* 9% concerned *'Personnel costs intern (lawyer, sales etc.), 2007 to 2010',* 2% was related to *'Personnel costs external (lawyer, etc.), 2008 to 2010'* and the remaining 2% regarded *'Travel expenses, 2008 to 2010'.*[10]

ECHA notes that, until the dispute claim was lodged on 22 January 2016, despite the Claimant's repeated requests to receive a transparent breakdown of the Lead Registrant's costs,[11] the Other Party had not provided the Claimant with a detailed itemisation of those costs. Instead, the Other Party limited itself to providing generic explanations as justification of those costs.[12] However, as the Claimant correctly pointed out,[13] the explanations provided by the Other Party on the Lead Registrant's costs were not sufficient to understand the basis of the cost calculation. As ECHA points out in its '*Practical advice for data sharing negotiations'*,[14] a potential registrant has "*the right to ask for more information if the cost breakdown* [they] *receive is not detailed enough"*. The right to request for a clear itemisation of all relevant costs, both data related and administrative costs has also been confirmed by the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data sharing.[15] The failure of the Other Party to deliver a transparent cost breakdown of the Lead Registrant's costs after several months of negotiations during which the Claimant had repeatedly requested this information is considered as lack of efforts to negotiate access to data and its costs in a transparent way.

In addition, the Other Party justified the delays in providing the requested information to the Claimant with the requirement of obtaining the prior approval of all the Consortium members.[16] ECHA highlights that any party in data sharing negotiations is free to establish

[6] See references no. 7 and 9.
[7] See references no. 8 and 16.
[8] See reference no. 25.
[9] See references no.26, 27, 30, 31 and 33.
[10] See reference no. 34.
[11] See references no. 16, 17, 19, 21, 22, 24, 26, 29, 30, 31, 33 and 35.
[12] See references no. 7, 9, 25 and 34.
[13] See reference no. 26.
[14] See section *4. Request a cost breakdown* of the *Practical advice for data sharing negotiations* available at http://www.echa.europa.eu/web/guest/support/registration/working-together/practical-advice-for-data-sharing-negotiations.
[15] See Article 2(1) and (2) of the Commission Implementing Regulation.
[16] See references no. 20, 23 and 32.

their internal structures and working methods. However, making every effort in sharing the data and their related costs requires from the parties to ensure that any such structure or working method may not impede on fulfilling their obligations under REACH, including those towards the other party in data sharing negotiations.

ECHA further notes that, based on the SIEF agreement[17] and as further explained[18] by the Other Party, the costs for the LoA to the joint submission included the amount of [redacted] for the Lead Registrant's costs regardless of the specific tonnage band of an individual registrant. The Claimant pointed out that this amount appeared to be *'disproportionately high when compared to the cost for access to the study data required for registration at* [redacted][19] ECHA notes that each registrant is only required to share the costs of information that it is obliged to submit to the Agency. This requirement applies to all relevant costs, both administrative and data related costs, as also confirmed by Article 4(1) of the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data sharing. If a registrant was required to pay for costs that are not relevant to the information requirements applicable to its registration, this would undermine the balance achieved by the REACH legislation between costs and information.[20] Accordingly, since preparing a dossier for a lower tonnage band would in principle require a smaller workload than preparing a dossier for a higher tonnage band, this difference should be naturally reflected in the final costs to be paid by a registrant. Therefore, charging the same amount for the Lead Registrant's costs to all registrants, without taking into account their respective tonnage bands, is de facto unfair and discriminatory, unless there are legitimate and justifiable reasons for charging the same costs to all registrants regardless their tonnage band. The Other Party however failed to justify the apparent unfair and discriminatory nature of the Lead Registrant's costs during the data sharing negotiations with the Claimant.

On 19 January 2016, after noting that '*a detailed, itemised, breakdown of the costs has not been provided',* the Claimant requested '[a]*s a matter of urgency*' information on the LoA costs to a number of studies included in the joint registration for the substance.[21] The Claimant provided to the Other Party five working days to reply to that request. The Claimant also indicated that, if the Other Party was not able to provide that information within the set deadline, it would expect to '*at least* [be] *provide*[d with] *details on how* [the Other Party] *intend*[s] *to calculate the cost for access to each* [of those] *stud*[ies]'.[22] However, on 22 January 2016, prior to the expiry of the deadline set to the Other Party and without prior warning, the Claimant submitted its dispute claim to ECHA. As ECHA points out in its *'Dos and Don'ts for data sharing negotiations'*, the parties should '[g]*ive the other party a fair and reasonable amount of time to reply*'.[23] ECHA notes that, filing a dispute before the deadline the Claimant itself had set to the Other Party for a reply to its request,

[17] SIEF agreement concluded between parties on 20 December 2010.
[18] See references no. 9, 25 and 34.
[19] See reference no. 16.
[20] See by analogy, for the balancing between costs and information achieved by REACH, the decision of the Board of Appeal of 23 September 2015 in the appeal case A-005-2014 Akzo Nobel Industrial Chemicals GmbH and others, at paragraph 86.
[21] See reference no. 34.
[22] *Ibid.*
[23] See the list of Dos and Don'ts for data sharing negotiations available at http://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations/dos-and-donts-for-data-sharing-negotiations.

and without previously warning the latter on its intention, is not a good data sharing practice. Nonetheless, ECHA acknowledges that, when the Claimant submitted its dispute claim on 22 January 2016, it had already requested repeatedly for several months from the Other Party a transparent breakdown of the Lead Registrant's costs. This information was however never provided by the Other Party. Thus, the Claimant was justified to consider that the negotiations had already reached a stalemate when it informed ECHA on the failure of the negotiations between the parties.

Against this backdrop, ECHA concludes that the Other Party has effectively caused the failure of the data sharing negotiations by not providing a transparent breakdown of the Lead Registrant's costs and by charging the same amount for those costs to all registrants regardless of their individual tonnage band. In addition, while the Other Party was free to choose the way it deemed fit for conducting the data sharing negotiations with the Claimant, it nevertheless failed to ensure that the selected working method of requesting the prior approval of the Consortium members would not hinder the timely progress of the negotiations and their conclusion. The Other Party thus failed to comply with its obligation to make every effort to share the data and its costs in a fair, transparent and non-discriminatory way.

In contrast, the Claimant acted in full respect of their obligation to make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way, by requesting a transparent breakdown of the Lead Registrant's costs, which could enable it to understand the basis of the cost calculation for the LoA, and by challenging the Other Party's arguments in a reasoned way.

Therefore, ECHA grants the Claimant permission to refer to certain data submitted by the Other Party which are listed in Annex I to the present decision. Additionally, ECHA provides the Claimant with the token to the joint submission for the substance, to ensure that after the dispute resolution, the Claimant's registration dossier will be part of the existing joint registration for the substance.

[redacted]

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Annex III to decision [redacted]

FACTUAL BACKGROUND REGARDING THE DATA SHARING NEGOTIATIONS

Ref. no.	Date	Content	Remark
1	09/07/2009 – 26/07/2012	SIEF communications between the Claimant and the Other Party. SIEF agreement concluded on 20 December 2010.	Provided only by the Other Party
2	13/02/2015	The Claimant re-establishes contact to the Other Party stating that they are members of the SIEF for the substance and *have made a registration payment* for the tonnage band [redacted] and would like to be informed about the cost of upgrading the registration to the next tonnage band [redacted].	Provided only by the Other Party
3	04/03/2015	The Claimant reminds the Other Party of the message of 13/02/2015	Provided only by the Other Party
4	05/03/2015	The Other Party confirms the receipt of the message and asks for *some patience* since they *are currently updating the LoA prices […].*	Provided only by the Other Party
5	23/03/2015	The Other Party clarifies that in 2011 the Claimant *did an advance payment of 50% of the total estimated price* for the tonnage band [redacted]. The cost was estimated to [redacted] and was based on consideration of 16 companies interested in registration of the substance, while the Claimant pre-paid [redacted] *as contribution to partially compensate the running cost* for the joint submission. According to the Other Party, the number of companies actually sharing the cost is only 3 (including the Claimant) and therefore *the additional cost for the requested upgrade* to [redacted] amounts to [redacted] The Other Party explain to the Claimant that the communicated cost consists of the reminder payment for tonnage band [redacted] (which *is not liable to interest rate and surcharge due to [the Claimant's] advance payment*) and additional amount of [redacted] for the LoA for tonnage band [redacted] (which *is liable to interest and surcharge*).	Provided only by the Other Party

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Ref. no.	Date	Content	Remark
6	03/06/2015	The Claimant informs the Other Party of having paid an instalment for the Letter of Access (LoA) *in the light of increasing cost with time* and requests clarifications regarding the calculation of respective amounts to be paid and the number of registrants sharing the cost. In particular, the Claimant requests to be provided with the breakdown for [redacted] cost of *Lead Registrant (Consortium & Management Tasks, travel expenses 2007-2010' (hereinafter referred to as 'the Lead Registrant's costs)*.	
7	16/06/2015	The Other Party provides explanations to various elements of cost calculation and the number of registrants sharing the cost. Regarding the cost of *Consortium & Management Tasks* the Other Party explains that *several experts (chemists, toxicologists, etc), managers, lawyers and other experts […] were […] involved. Contracts had to be reviewed, bank accounts had to be opened, discussions on C&L issues, studies to be initiated, and, and, and. […] If the cost appears excessive* to the Claimant, The Other Party makes a reference to ECHA article in Newsletter of April 2015 *'Authorisation: it's a business choice*[24], in which there is a statement that *[another company] estimates that the cost for the joint application is around EUR* [redacted]*. Approximately half of this was spent on managing the consortium and the other was for the application itself.* Based on that statement, the Other Party explains that [redacted] were spent on consortium management.	
8	06/07/2015	The Claimant replies that the reference of the Other Party to the ECHA Newsletter is *not a fair comparison as the [Other Party] case refers to authorisation while [the Claimant] is dealing with registration* and requests clarifications on this matter as well as clarification on the number of companies that have actually shared the cost of the dossier so far.	
9	08/07/2015	The Other Party replies that [redacted] *spent on managing the consortium for authorisation […] shows the magnitude of cost.* In case of the substance for registration, the compensation requested by the Other Party corresponds to 1/8 of the total management cost. The Other Party confirms that number of companies to share the cost for the dossier is 2 (including the Claimant).	
10-15	21/07/2015 22/07/2015 09/09/2015 09/09/2015 14/09/2015 16/09/2015	Discussion between the Claimant and the Other Party regarding access to dedicated secure web portal and analytical methods for substance identification.	Provided only by the Other Party

[24] http://newsletter.echa.europa.eu/home/-/newsletter/entry/2_15_authorisation-its-a-business-choice

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[redacted]

Ref. no.	Date	Content	Remark
16	13/10/2015	The Claimant states that the amount of [redacted] *seems to be disproportionately high when compared to the cost for access to study data required for registration.* The Claimant continues their view, that *a surcharge is already applied to the cost of each study, which covers administrative expenses […]* and requests to be provided *with a detailed, transparent breakdown of the costs.* The Claimant is of the understanding that *Consortium is responsible for about 45 […] substances under REACH* and requests the confirmation that consortium costs subject to compensation refer only to the one substance to be registered by the Claimant. Finally, the Claimant enquires about the possibility to obtain a reduction in the fee for the substance, given that the Claimant is an SME.	
17	20/10/2015	The Claimant requests the confirmation that the message of 13/10/2015 has been received and indication when they will be provided with a response.	
18	21/10/2015	The Other Party confirms the receipt of the message and that they will answer *as soon as possible.*	
19	09/11/2015	The Claimant requests the information when their message of 13/10/2015 will be answered.	
20	12/11/2015	The Other Party explains that the prepared reply for the Claimant has been approved only by one member of the consortium so far and that reminder was sent to other members.	
21	19/11/2015	The Claimant repeats the request for the information when their message of 13/10/2015 will be answered, given that *it has been over 5 weeks now since [they] sent the initial enquiry.*	
22	26/11/2015	The Claimant requests the information when their message of 13/10/2015 will be answered, given that it has been *over 6 weeks ago.*	
23	01/12/2015	The Other Party informs that *the draft reply has not been approved by one […] consortium member yet* and that *a reminder was sent today.* The Other Party continues that *as consultant cannot exactly advise when [the Claimant] can expect a response.*	
24	01/12/2015	The Claimant reacts that *responses regarding data sharing should be provided in a timely manner* and that the *Commission Implementing Regulation on joint submission of data and data sharing expected to be published early next year states that the itemisation of costs shall be provided to the potential registrant without undue delay.*	
25	03/12/2015	The Other Party replies to the message of 13/10/2015. Regarding the [redacted] management cost they point out that *the cost estimation was part of the SIEF Agreement […] that were accepted by signing […] SIEF Agreement and paying the pre-payment of* [redacted] *(considering in total 16 companies interested in registration […]).* The Other Party continues that the problem is not the management cost *but the actual small number of cost sharing companies which boost the LoA prices.*	

[redacted]

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Ref. no.	Date	Content	Remark
		The Other Party agrees that cost to access for studies is *quite cheap* compared to management cost for the reason that *a lot of expensive studies are read-across* and due to *the high and fair read-across deduction (70%).* The Other Party also confirms that *the surcharge of 4-25% per study represents administrative expenses per study* and that *a breakdown will be available after 2018 in the course of reimbursement calculation.* They continue that *management costs were proportionately divided* among all substances managed by the consortium. The Other Party states also that *SME reduction is not part of the SIEF Agreement [which] obliges to participate in all costs.* They inform also that *prices are fixed until end of 2015* and that *in the meantime, an additional company purchased a LoA […] which lowers the LoA prices a little:* [redacted]*: nearly* [redacted] *less.*	
26	11/12/2015	The Claimant states that the Other Party *provided detailed information on how the costs of the studies have been calculated therefore [the Claimant] would expect the same kind of detailed breakdown for the other costs.* The Claimant requests to be provided with a detailed breakdown of [redacted] administrative cost along with *evidence that the management costs have been shared proportionately across [all consortium] substances.* The Claimant refers to provisions of SIEF agreement regarding opt-out and requests clarifications on the *costs involved in purchasing access only to specific studies*. The Claimant also asks for confirmation that *any deposit already paid […] would count towards the costs of purchasing access to any [individual] studies.*	
27	22/12/2015	The Claimant asks when they *are likely to receive a response to the message* of 11/12/2015	
28	23/12/2015	The Other Party informs that *due to the holiday season [they] cannot come back […] before beginning of the next year.*	
29	24/12/2015	The Claimant informs to *hope [the Other Party] will be able to send a response during first week of January [2016].*	Provided only by the Other Party
30	07/01/2016	The Claimant reminds about the message sent on 11/12/2015.	
31	12/01/2016	The Claimant requests an update and response to the message of 11/12/2015.	
32	13/01/2016	The Other Party informs that *the item was discussed [in] the last consortium conference call in December and is still under discussion* and asks the Claimant *for some more patience.*	
33	13/01/2016	The Claimant indicates that they *have been very patient so far considering that the prior response took nearly 8 weeks* and requests *a response by next week.*	

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Ref. no.	Date	Content	Remark
34	19/01/2016	The Other Party replies to message of 11/12/2015. The Other Party explains that share of administrative cost of [redacted] allocated for the substance to be registered by the Claimant is 20% of total administrative costs of [redacted] for all substances in the portfolio. They explain further that 87% of those costs referred to *'Personnel costs intern (REACH-Team, Product Safety), 2007 to 2010',* 9% concerned *'Personnel costs intern (lawyer, sales etc.), 2007 to 2010',* 2% was related to *'Personnel costs external (lawyer, etc.), 2008 to 2010'* and the remaining 2% regarded *'Travel expenses, 2008 to 2010'.* Regarding the itemisation and justification of these costs, the Other Party states that *transparency with regard to the costs was given by the cost compilation given in the SIEF Agreement (standard contract from CEFIC with detailed indication of costs, studies and calculations).* Regarding opt-out possibility by the Claimant, the Other Party is of the opinion that *opt out is an option in case of for example of different substance ID.* The Other Party informs that *the prices are valid for JS (member dossier), not for LoA to certain studies. LoA price for certain studies is higher due to additional administrative work.* The Other Party continues that the Claimant *paid a prepayment to the JS, i.e. LoA to all studies being relevant for this tonnage band, not for LoAs to certain studies.* The Other Party concludes with statement that *there are about 400 SIEF members […]but unfortunately nearly none of them seems to be interested in purchasing an LoA. Consequently, the LoA prices are quite high.*	
35	19/01/2016	The Claimant replies that *a detailed, itemised, breakdown of the costs has not been provided*. The Claimant also requests to be provided with information on cost of LoA only for 14 studies [redacted], stating that they are expecting *response within 5 working days.* The Claimant adds that if the Other Party *is unable to meet this deadline for providing the cost for access to each of the […]studies,* the Other Party is requested to provide details of how they intend to calculate the cost for access to those studies.	

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