[redacted]

Helsinki, 13 October 2016

[redacted]

represented by:

[redacted]

Copy to:

[redacted]

Decision number: [redacted]
Dispute reference number: [redacted]
Name of the substance: [redacted]
EC number of the substance: [redacted]

DECISION ON A DATA SHARING DISPUTE

1. Decision

Based on Article 30(3) of Regulation (EC) No 1907/2006 ('REACH Regulation'),

ECHA does not grant you the permission to refer to the information you requested from [redacted] of the above-mentioned substance.

The reasons of this decision are set out in Annex I. Advice and further observations provided in Annex II. The factual background of the dispute described in Annex III.

2. Procedural history

On 27 July 2016, you (the 'Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with [redacted] (the 'Other Party') as well as the related documentary evidence to ECHA. To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA also requested the Other Party to provide documentary evidence regarding the negotiations. The Other Party submitted the documentary evidence on 18 August 2016, as requested by ECHA.

[redacted]

3. Appeal

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

Yours sincerely,

Christel Schilliger-Musset[1]

Director of Registration

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

[redacted]

Annex I: REASONS OF THE DECISION

Article 29 of the REACH Regulation states that parties whose information is held by ECHA in accordance with Article 15 are participants of the Substance Information Exchange Forum (SIEF). Thus, an applicant who submitted information to ECHA pursuant to the Biocides Products Regulation[2] ('BPR') is subject to data sharing obligations within the SIEF for this same substance.

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, 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 requires the parties to negotiate the sharing of data and related costs as specifically and clearly 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.

Making every effort also means that the Claimant shall only submit a dispute to ECHA as a last resort, after exhausting all the arguments and efforts. It is indeed the primary responsibility of the parties to discuss and negotiate on the sharing of data, exercising contractual freedom. ECHA's competence is only limited to assessing if every efforts were made to reach an agreement. The data sharing dispute process is not a substitute to negotiations. Thus, the permission to refer to the requested studies is only granted when the Claimant submits the dispute as a last resort, after having made every effort to reach an agreement.

Assessment

The initial negotiations between the Claimant and the Other Party focused mainly on clarifying what type of dossier(s) (and for which substance) was available or planned to be submitted, for which tonnage band and for which regulation (REACH or BPR)[3]. The Other Party indicated that they have '*a full biocide dossier of data [for the substance in question], which is currently under evaluation by the BPR authorities*' as well as an on-site isolated intermediate dossier under REACH[4]. The Claimant required access to studies to submit a registration fulfilling the data requirements of Annex VII and VIII of REACH, i.e. for tonnage band [redacted] tpa, specifying that it would make its own IUCLID compilation and the Chemical Safety Report (CSR)[5].

ECHA notes that the Other Party was slow in giving replies at the beginning of the

[2] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1.
[3] See document reference no. 2, 3, 7
[4] See document reference no. 14
[5] See document reference no. 15

[redacted]

negotiations[6]. However, in the balance of efforts, it can be recognised that both parties were in general giving timely replies and that this initial slowness did not impair the overall negotiations.

In data sharing negotiations, the definition of the data and other cost items to be shared is essential to reach an agreement. ECHA notes that the parties have been discussing both on which endpoints the Claimant wanted to get access to and on the necessary data to fulfil these endpoints. However, many points in these discussions are still open. The Claimant asked for the list of studies and costs itemisation and the Other Party provided it, in a spreadsheet format. However, it appears that the Claimant was not sufficiently clear in indicating the specific studies they would like eventually to get access to. For example, the Other Party suggested to share all the available studies to fulfil the physico-chemical endpoints while the Claimant explicitly indicated that they do not need the physico-chemical studies[7]. At the same time, the Claimant indicated in their counter offer to the cost itemization provided by the Other Party that they were interested in two studies for physico-chemical endpoints[8]. Therefore, in order to make every effort, the Claimant needs to be more clear and precise in specifying what they request, to make sure that their request can be met.

On the other hand, the Other Party provided detailed replies to the Claimant (for example clarifying that in case more companies will be interested in the registration of the substance, a reimbursement scheme will apply[9]) and made efforts in assessing what studies could correspond to the REACH endpoints. ECHA acknowledges that since BPR and REACH have different information requirements, the discussions on the studies corresponding to the REACH requirements in a situation such as the present one can take time. ECHA, however, notes some misunderstandings on the side of the Other Party, for example concerning the preparation of the IUCLID file. The Claimant informed the Other Party that they will prepare their own IUCLID file and yet the Other Party included this cost item to their offer[10], without making clear to what this cost is related. Thus, both parties would need to clarify their position on some issues.

As a result of the data sharing and joint submission obligation, discussions on the adequacy of the information to submit a registration dossier are expected within a SIEF. Data owners might be supportive to potential registrants, in particular when they are smaller companies. Indeed, they may have a better regulatory knowledge and can help potential registrants with issues related to the adequacy of the data. While it is the responsibility of each registrant to fulfil their data requirements under the REACH Regulation, it is the competence of ECHA to verify the compliance of this data. Therefore, a data owner cannot use an argument based on the adequacy of the data of a (potential) registrant to impair data sharing negotiations.

When looking at the negotiations regarding the Letter of Access ('LoA') offer, e.g. discussion on the studies necessary to fulfil some endpoints, it appears that the Other Party engaged into discussions on the quality of the data for the Claimant's future registration. However, ECHA notes that these discussions did not block the negotiations. First, it appears that the Other Party was trying to understand the Claimant and to explain the different issues concerning the data, also by involving its legal and scientific experts and sharing their

[6] See document reference no. 4, 5 and 16.
[7] See document reference no. 20, 22, 23
[8] See document reference no. 34
[9] See document reference no. 38
[10] See document reference no. 14, 15, 23, 26, 34, 38

[redacted]

inputs[11]. As a sign of an effort to move on with the negotiations, the Other Party was also open to adapt their LoA offer to what was requested, by taking into account the Claimant's comments, replying to them and by removing some studies from their offer.[12] In the last email before the submission of the dispute, the Other Party proposed a phone conference to clarify the remaining issues. Thus, the negotiations were still progressing at the moment of the submission of the dispute by the Claimant.

One of the other aspects raised during the negotiations concerned the *'discount for REACH only use'*,[13] which directly affects the final LoA price. The parties exchanged only one round of arguments on the issue, which were rather superficial and did not address it in depth why they consider their proposed discount as appropriate. In view of finding an agreement on this issue, further discussion seems to be needed to explain the position of each party.

ECHA acknowledges that the Claimant indicates to be an SME and, therefore, may have limited resources available. However, irrespective of the size of the company, a party wishing to fulfil their data sharing obligation under REACH needs to be open to discussion and to explain their position. During the negotiations, the Claimant indicated that the LoA price was disproportionate and repeatedly referred to the Commission Implementing Regulation (EC) 2016/9 highlighting its '*very clear*'[14] rules on how to share data in fair, transparent and non-discriminatory way. This reference was one of its main counter argument to the price and the scope of the LoA, with emphasis that potential registrant has to pay only for the data relevant for their tonnage band and that there is no need for additional costs.[15] Nevertheless, merely referring to the Implementing Regulation is not enough. In order to make every effort, they should be clearer on what it implies for their specific negotiations, in order to explain their position and allow the negotiations to progress. When assessing the efforts made by both parties, it should be noted that the above-mentioned issues are still open to further discussion. The Other Party did not block the negotiations and was open to discussing and adapting its offer. Thus, both parties need to continue their efforts to reach an agreement.

Conclusion

Based on the above, ECHA concludes that at the time when the Claimant submitted the dispute claim, 27 July 2016, the negotiations had not reached a standstill and thus the parties had not exhausted all their efforts to reach an agreement on sharing data.

ECHA reminds that parties are obligated to make every effort to come to an agreement. They cannot merely insist on their positions without explaining it. They must seek to find a common understanding on the data to be shared by addressing each other's concerns, e.g. on the costs, etc. Once a potential registrant requests for data to be shared, both parties have to make every effort in their negotiations.

ECHA considers that the Other Party did not block the negotiations while the Claimant did not exhaust yet all available means and therefore still remains with a possibility to make further effort in the negotiations and reach a fair, transparent and non-discriminatory agreement.

[11] See document reference no. 39
[12] See document reference no. 44
[13] See document reference no. 34, 38
[14] C.f. document reference no 30
[15] C.f. document reference no. 26, 32.

[redacted]

Consequently, ECHA does not grant the Claimant permission to refer to the data submitted by the Other Party. Both parties are encouraged to carry on with the negotiations and to take into consideration the observations made by ECHA in the present decision. This does not exclude the possibility to submit again at a later stage a new dispute to ECHA, as a measure of a last resort.

Annex II: ADVICE AND FURTHER OBSERVATIONS

ECHA stresses that both parties still share the common data-sharing obligation and are still required to make every effort to reach an agreement on the sharing of the information and the related costs. Therefore, ECHA would like to make some general observations in order to facilitate a future agreement.

In order to make every effort, the parties need to seek solutions on disagreed matters.

In general, both companies should consider the following:

- To have a clear strategy line and be consistent in the scope of the LoA:
    - The precise list of studies the Claimant was seeking access to did not became entirely clear during the negotiations. Making every efforts requires clear indication of the needs of the Claimant. Further discussions, and for example a phone conference as proposed by the Other Party[16], could help to clarify the scope of the LoA and keep on progressing in the negotiations.
    - The applied *'discount for REACH only use'* used in the LoA price calculation has a significant impact on the final LoA price. The difference in the used figures was not justified by any party. Therefore, it is essential to negotiate more in details this cost factor while justifying its fair, transparent and non-discriminatory nature.
- Finally, ECHA recommends that both parties agree to be part of the same joint submission.

[16] C.f. document reference no. 44.

[redacted]

Annex III: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

Ref. no.	Date	Content	Remark
1	11/05/2015	The Claimant contacts the Other Party to ask about the price of the letter of access and which studies Lead Registrant owns for [redacted] to be used as a read-across for the registration of [redacted]	
2	12/05/2015	The Other Party informs that they have registered [redacted] as a strictly controlled [redacted] and they plan to register [redacted] within the next 12 months as a [redacted]. The Other Party also informed that most uses of [redacted] in the European Union are covered by the Biocidal Products Regulation rather than REACH. The Other Party further asks *'Which kind of REACH registration do [Claimant] plan?'*.	
3	12/05/2015	The Claimant confirms that they plan to register the [redacted] in the scope of REACH for the tonnage band [redacted] t/y. The Claimant requests access to [redacted] for the [redacted] to be used as a read-across.	
4	25/06/2015	The Claimant reminds that they did not get any answer to their previous message.	
5	20/07/2015	The Claimant repeats their request to receive the price of the letter of access for toxicological studies and the list of studies the Other Party owns for [redacted] to be used as a read-across for the registration of [redacted] and for the purpose of REACH in the tonnage band [redacted] t/y.	
6	24/07/2015	The Other Party asks contact details of the representative of the Claimant in order to carry on the negotiations.	Provided only by the Claimant
7	30/07/2015	The Claimant proposes a meeting *'to have a first evaluation about* [redacted] *tox data'*.	

[redacted]

Ref. no.	Date	Content	Remark
8	09/10/2015	The Other Party responds to the request of the Claimant and explains that the data for [redacted] they own is worth of [redacted], and all uses are covered under the Biocidal Products Regulations. They further mention that they recently REACH registered [redacted] as a [redacted] with very little data contained in the dossier. The Other Party expresses their belief that the Claimant might not expect to pay [redacted] Euros for a joint access to a complete biocides dossier. The Other Party agrees to meet with the Claimant to find a suitable way forward. Finally, the Other Party emphasised that [redacted] is registered as a [redacted] and they doubt that read across to such limited data would be of much help.	
9	09/10/2015	The Claimant confirms that their application is not biocidal and informs that their representative will come back to the Other Party with a detailed request.	
10	09/10/2015	The Claimants proposes a time for the phone conference to discuss details for the possible solution.	
11	09/10/2015	Arrangements for the phone conference.	
12	09/10/2015		
13	27/10/2015	The Claimant asks if the Other Party had time to check whether an access to some of the studies that the Other Party had performed on [redacted] and the corresponding price would be available.	
14	28/10/2015	The Other Party informs the Claimant that their legal team is working on the proposal document. Additionally, the Other Party summarizes the main points from the call conference: • The Claimant wish to REACH register [redacted] for [redacted] T. • The Other Party has a full biocide dossier of data on [redacted], which is currently	

[redacted]

Ref. no.	Date	Content	Remark
		under evaluation by the BPR authorities, as well as a REACH registration for [redacted] as a part of a joint submission. • The Other Party's biocides dossier contains study summaries in Word format as was required by the Biocidal Products Directive in 2007 and 2008. • The Other Party suggests to the Claimant: (1) to register as a member within existing REACH joint submission and to update dossier to cover Annex VII and VIII REACH data; or (2) to create another joint submission for a full registration – for both strategies Annex VII and VIII data needs to be put into IUCLID and Chemical Safety Report should be created. • The understanding of the Other Party is that the Claimant initially asked *'about a letter of access to specific studies - presumably because the only data visible in the ECHA database was the [Other Party's] data on* [redacted] *rather than any data on* [redacted]*?'* • *'The requested data are* [redacted] *(not Annex VII or VIII) and unspecified environmental data.'* • It was agreed that the Other Party should propose a way forward on data sharing for consideration by the Claimant.	
15	02/11/2015	The Claimant intends to prepare own IUCLID file and CSR. They confirm that they have asked only information for the human health endpoints. Because [redacted] *is completely empty'* they have not specified any list.	Only provided by the Other Party
16	30/11/2015	The Claimants wants to know if the Other Party has any news regarding their requests. They inform the Other Party that they need to register and if within a week the Other Party will not respond to their request the Claimant will go for an individual registration.	
17	30/11/2015	The Other Party agrees that it is a priority for them and they endeavour to prepare a respond.	
18	03/12/2015	The Other Party informs the Claimant that they will send a draft collaboration agreement and an estimate of the Letter of access cost for Annex VII and VIII	

[redacted]

Ref. no.	Date	Content	Remark
		REACH data. However, an input from tox and ecotox experts is required to determine appropriate costing for [redacted] – thus it will take one week longer.	
19	03/12/2015	The Claimant asks their representative to identify to the Other Party which data the Claimant needs.	
20	03/12/2015	The representative of the Claimant states that they do not need the full data set and they will come to the Other Party on the next day.	Only provided by the Other Party
21	03/12/2015	The Other Party requests the Claimant to share their data on [redacted] if they have any. This is needed in case a substance is listed for the substance evaluation and the Claimants data could adversely affect the evaluation of a product that is very important to the Other Party.	
22	04/12/2015	The Claimants responds to the Other Party that they don't have own data but '*there is a NTP [National Toxicology Program] report which is public and covers* [redacted]*'.* The Claimant needs only: [redacted] The Claimant proposes two options for consideration: 1. LoA to the full Annex VIII requests 2. LoA to the selected studies	
23	10/12/2015	The Other Party expresses the concern because their dossier was developed for the BPR requirements and the Claimant would need to adapt these data for REACH registration. The Other Party identifies the following issues: 1. They have only [redacted], whereas [redacted]	Attachment provided only by the Other Party

[redacted]

Ref. no.	Date	Content	Remark
		[redacted] is required for a [redacted] T dossier. 2. They has several [redacted] studies and all (except one) of them needs be taken into account to correctly address this end-point. 3. They have [redacted] study as opposed to the [redacted] study required for REACH Annex VIII. The NTP study has some deficiencies in it. 4. They have full [redacted] studies for [redacted] rather than just a screening evaluation. Data for one specie is in their calculations for LoA price. 5. They have full [redacted]) data needed for the risk assessments [redacted]). 6. [redacted] is necessary to correctly conclude on [redacted] endpoint. 7. The studies for [redacted] had to be used. Considering the above points the Other Party indicates the following study costs: REACH Annex VII: [redacted] REACH Annex VII + VIII: [redacted] The Other Party further indicates that the calculation of final cost for LoA should take into account: • Agreed increment to cover admin/study monitoring costs • Increment to cover a risk premium. • Increment to cover the work required to summarise all the data in IUCLID. • Number of companies benefitting from the data • Decrement for REACH-only use The Other Party provides a document based on the CEFIC template including some typical values for the LoA cost calculations. Finally the Other Party states that *'[h]igh LoA prices are quite normal for REACH registrations of substances that are also biocide actives'*.	
24	24/01/2016	The Claimant notes that the Other Party's offer is disproportionate for a REACH registration for the tonnage band [redacted] t/y and asks the Other Party to reconsider	

[redacted]

Ref. no.	Date	Content	Remark
		their offer.	
25	25/01/2016	The Other Party agrees that costs are higher than usually expected, but they are of opinion that *'detailed scrutiny of the data that underpins each end-point allows a higher figure to be justified'.* The Other Party suggests to appoint an independent consultant, agreeable by both parties, who would make an assessment of the amount to be paid and both parties agree to be bound by their recommendations. They are also open to better ideas.	
26	01/02/2016	The Claimant does not support the proposal of appointing an independent consultant. They point out that Article 15 of REACH considers biocides as already registered. Therefore a normal mechanism to calculate letter of access only for the required end-points should be applied. Additionally, the Claimant highlights that the following is foreseen in Implementing Regulation 2016/9 on data sharing: *'Article 1 asks for transparency by providing detailed cost of each single study that is requested for the registration. Article 4 (1) states that any registrant has the right to pay only what is requested according to own specific obligations. All costs must be equally shared among **all** registrants, included those who are participating in the biocide registration.'* Further the Claimant specifies that for either Annex VII or Annex VIII of REACH they need: [redacted] Costs are from the Fleischer list. This leads to a total of [redacted] € for Annex VIII and [redacted] € for Annex VII. This cost has to be shared among all registrants and	

[redacted]

Ref. no.	Date	Content	Remark
		cannot lead to a LoA higher than [redacted] for an Annex VIII registration and [redacted] for Annex VII. Finally, The Claimant emphasise that these costs only provide access to the studies, not covering IUCLID compilation and risk assessment. They are aware that risk management under REACH is different from biocides and therefore will prepare it themselves and add that *'[i]f your concern is that those single studies may lead to a conclusion that is different than yours, you may add whatever you like, but without increasing the costs.'*	
27	01/02/2016	The Other Party indicates that they need to consult their legal department and they still believe that it would be in the best interests of both companies to present the registration of Claimant as a member of the joint submission.	
28	02/02/2016	The Claimant informs the Other Party that the discussion on access to data have been going on since May 2015 and so far no positive solution has been found. They also establish the deadline of 9 February to receive the final feedback about data sharing and relative costs. If the Claimant does not receive any feedback by that date they plans to proceed independently and to inform ECHA about the situation.	
29	08/03/2016	The Other Party reiterates their willingness to share data and to enter into a joint submission according to OSOR principle. As no settlement on a letter of access price is achieved the Other Party suggests again to appoint an independent third party to assess the compensation price.	
30	08/03/2016	The Claimant does not see the need to nominate third party as *'the new ECHA guidelines are (luckily!) very clear'* and as the best practice for data sharing is well explained in the webinar by ECHA. The Claimant asks the Other Party to *'prepare a revised LoA according to the regulation 2016/9 on data sharing'* for tonnage band [redacted] taking also into consideration that many studies are public. The Claimant sets up 15/03/2016 as a deadline to receive the reply from the Other Party.	
31	11/03/2016	The Other Party remains convinced that agreeing on data sharing and joint	

[redacted]

Ref. no.	Date	Content	Remark
		submission is of mutual interest while making sure that the data on [redacted] provided to ECHA correctly represents the properties, hazards and risks of the substance. The Other Party is aware about the Claimant SME status but they don't see the possibility to offer a special price. The Other Party agrees to take more detailed look at the letter of access but it is unlikely to match the figure presented by Claimant in the email of 01/02/2016. The Other Party also points out that *'majority of the data in the public domain belongs to [the Other Party] and is still subject to REACH rules on data compensation. Article 10 (a) states that "… the registrant shall be in legitimate possession of or have permission to refer to the full study report .... for the purposes of registration".'* Finally the Other Party promises to send the revised LoA price as soon as it is reasonably practical.	
32	11/03/2016	The Claimant responds that they do not ask a special treatment but a fair treatment in accordance with Commission Implementing Regulation (EU) 2016/9. To fulfil the obligation for either Annex VII or Annex VIII of REACH, the Claimant needs detailed costs for the following items: [redacted]	
33	24/03/2016	The Other Party provides a detailed breakdown of costs as requested, *'where for data from a higher tonnage band used to address an Annex VII data requirement [they] have applied a factor to reduce the cost to [the Claimant] (or to other*	

[redacted]

Ref. no.	Date	Content	Remark
		companies subsequently making a similar request).' They also explain that in case the Claimant has some of their own data it would be considered and LoA price would be recalculated. They further ask the Claimant to share the summaries of studies owned by the Claimant in case the Other Party would need to take new, possibly more adverse, data for their own registrations. Finally the Other Party states that cost have been reduced significantly from the previous estimate. The current figure is [redacted] which compares to some LoA prices that the Other Party has been quoted for other substances at [redacted] tonnes.	
34	04/04/2016	The Claimant had assessed and revised the cost calculations and made counter offer of [redacted] per party. They further state the following: • They don't need [redacted] • They will repeat [redacted] and [redacted] as a function of [redacted] even if the results will not be satisfactory, because the price proposed by the Other Party is '*really too expensive and disproportionate*' for an Annex VIII requirement. • [redacted] is not Annex VIII requirement; [redacted] is enough. • They can accept only one [redacted] assay considering that it is not really necessary • [redacted] (extended) is redundant as there is the NTP report which is public and fulfils the REACH requirement for Annex VIII. • The [redacted] study is not needed because Annex VIII requires only available information. • ECHA has clearly stated in their latest webinar on data sharing that no risk premium should be charged. • REACH-only use should be 60% reduction and not 25% unless the Other Party is selling co-ownership of the studies. • The Other Party is splitting the final cost by 2 but it is not clear whether it is the final share for REACH purpose or it will be the final share per REACH registrant. There are already two other companies that are interested in the registration of	

[redacted]

Ref. no.	Date	Content	Remark
		[redacted] • The Other Party has registered [redacted]. The Claimant will prepare its own IUCLID and CSR for the use as substance. The Other Party cannot do that on behalf of the Claimant because the final use is confidential. In addition the Claimant mentions that there might be change because they are considering the registration of [redacted] instead of [redacted].	
35	04/04/2016	The Other Party agrees to take a detailed look at the points made by the Claimant. Additionally they ask if the Claimant reverts to a [redacted] registration, as the LoA price for it would be different because there is considerably less data available.	
36	15/04/2016	The Claimant reminds about the reply and confirms that for the moment the substance of interest is [redacted] and relevant data can be used for a read across.	
37	15/04/2016	The Other Party explains that they need time to consult their legal team.	
38	22/04/2016	The Other Party replies to the Claimant's point raised in email on 04/04/2016: **No need for [redacted] tests** The Other Party has submitted the full biocides dossier to the European Authorities, which also contains full set of [redacted] data. The Other Party presumes that if the Claimant generates own [redacted] data they would need to pay full price to generate the data and fees for ECHA for opting-out from REACH endpoints. If the Claimant buys the data from the Other Party they would pay only half of the cost and such studies are not expensive. [redacted] **and** [redacted] **as a function of** [redacted] is an important property for this substance, even if it is not important for the end-use of the Claimant. The Other Party expects ECHA to take the view that the hazard properties should be correctly represented in a REACH dossier, and the underpinning studies should be appropriately compensated. [redacted] **vs.** [redacted]	

[redacted]

Ref. no.	Date	Content	Remark
		The Other Party awaits an opinion from their toxicology expert. [redacted] are addressed in REACH Annex VIII [redacted]. [redacted] The Other Party awaits an opinion from their tox expert. It is their understanding that the full set of [redacted] studies is necessary to correctly address this end-point. [redacted] is the typical REACH study. However, the Other Party owns several [redacted] studies which address the [redacted] The Claimant specifically requested access to this data and it is discounted because the Claimant has to address Annex VIII rather than Annex IX. The NTP report may be used to support conclusions on [redacted] and [redacted] ([redacted]) but this report cannot be used to address [redacted] [redacted] The Other Party's data is existing information and it should be compensated. A discount is applied to account for the fact that only Annex VIII needs to be addressed by the Claimant. [redacted] The Other Party agrees to remove these charges *'as a gesture of goodwill'*. The Other Party further indicates that the application of a [redacted] was common practice for the 2010 and 2013 REACH registration deadlines. **Decrement for REACH-only use** The Other Party disagrees because according to them the 25% figure is typical for REACH. **Final share for REACH purpose vs. final share per REACH registrant.** The Other Party states that splitting the cost by two is correct because no other REACH LoA has been signed for this data. If another company pays for a LoA the	

Ref. no.	Date	Content	Remark
		Other Party will apply the same calculations as for the Claimant and will reimburse the Claimant to account for the involvement of an additional party. **Preparation of IUCLID file and CSR for use as substance** The Other Party agrees that the preparation of a CSR is not covered by REACH OSOR rules. The Other Party THPS is registered as a biocide under REACH because biocides in the BPR review programme are regarded as registered. The Other Party has also registered the same substance as an intermediate for REACH and the Other Party is the lead registrant for that registration.	
39	28/04/2016	The Other Party provides additional comments from their toxicologist. Substance sameness should be taken into account. If [redacted] from the Claimant has different p[redacted] properties to [redacted] from the Other Party then it is likely that the [redacted] data generated by the Other Party may be inapplicable for the Claimant substance. Regarding the [redacted] studies, it is not mandatory at [redacted] to have [redacted]. The Other Party considers the [redacted] to be the most appropriate for industrial use of this substance and thus [redacted] is not needed. Regarding [redacted], the Claimant should buy access to the [redacted] (which was negative), the [redacted] and also t[redacted] and [redacted] (which were also negative). The most important thing is that the positive results observed in the [redacted] explain the focus on the two [redacted] studies that are assessing the [redacted]. In addition, the [redacted] under Annex VIII of REACH is required in that case. So the whole package of [redacted] should be purchased. The one exception is the [redacted] which is not recognized anymore.	

Ref. no.	Date	Content	Remark
		It is correct that the NTP report addresses only [redacted] and [redacted] requirements. The Claimant should buy access to the [redacted] ([redacted] that leads to the [redacted] This may be sufficient, as REACH states that it is not necessary to do an additional [redacted] ([redacted]) if the previous leads to classification. The Claimant could theoretically do their own [redacted] based on available data they should buy from the Other Party (i.e. [redacted] etc...). However, the Claimant will need to compile a CSR and a correct understanding of [redacted] is important for deriving the DNEL for the risk assessment. [redacted] should be the focus for industrial use of [redacted]	
40	22/06/2016	The Claimant explains that they have delayed their response because they wanted to clarify some of data sharing points with ECHA during the 11th stakeholder day. They remind again the main principle of the data sharing; it is not for profit and each registrant needs to pay only for the data required for specific tonnage band. The Claimant insists that the cost should be closer to the proposal they made earlier required for [redacted] t/y. In this proposal p[redacted] tests are not included because in the offer of the Other Party those are more expensive than doing it again with an advantage to own these tests. The Claimant agrees that the substance sameness is very important and they ask the Other Party to share their SIP. Finally the Claimant inform the Other Party that if no agreement will be reached by 10 July they will '*ask for an opt-out submission to ECHA*'.	
41	01/07/2016	The Other Party agrees that the Claimant and they have different view on the LoA price and repeat that an independent third party should be appointed. They further explain that the same data is used for REACH and Biocides and the data sharing rules are largely comparable. Finally they confirm that they are open to further	

[redacted]

Ref. no.	Date	Content	Remark
		negotiations but in case the Claimant addresses the issue to ECHA they *'should be prepared to defend [their] refusal of independent arbitration*'.	
42	02/07/2016	The Claimant reminds that on 28 April the Other Party wrote that their toxicologist approved the approach of the Claimant. After that there has not been update on the Other Party's proposal and thus they ask the Other Party to send an update.	
43	13/07/2016	The Claimant informs the Other Party that as they have not received any feedback they will launch a data sharing dispute and ECHA can act as a third party as the Other Party was suggesting.	
44	14/07/2016	The Other Party provides new reduced cost offer for the LoA by removing cost of the [redacted] study and the [redacted]. As before the main concerns of the Other Party are: • To be fair, transparent and non-discriminatory to all company whether they are interested in REACH or Biocides. • To ensure that disseminated information properly informs all stakeholders of the correct hazard profile of [redacted]. The Other Party highlights importance *'to arrive at a position which is agreeable to both companies and which is seen as treating everyone fairly'.* Therefore the Other Party invites the Claimant to participate in a conference call with the following points: [redacted] 5. Others They invite the Claimant to add other items if needed.	
45	18/07/2016	The Other Party corrects the offer LoA price communicated in their previous	

[redacted]

Ref. no.	Date	Content	Remark
		message; it should have been [redacted] rather than [redacted].	