EUROPEAN CHEMICALS AGENCY

[redacted]

25 -11- 2015

Prospective Applicant:

[redacted]

Copy to Other Party:

[redacted]

Sent via encrypted email and registered mail

Reference number of the dispute claim	DSH-63-3-[redacted]2015
Decision number	DSH-63-3-D-[redacted]2015
Name of active substance	[redacted]
EC number of the substance	201-186-8

DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 63(3) OF THE BIOCIDAL PRODUCTS REGULATION (EU) No 528/2012 (BPR)

Dear Mr[redacted],

On 21 August 2015, ECHA registered a claim you (the Prospective Applicant) submitted concerning the failure to reach an agreement on data sharing with [redacted] (the Other Party) as well as the related documentary evidence to the European Chemicals Agency (ECHA). Data sharing had been sought for an application to be included on the Article 95 list.

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 provided the requested documentary evidence on 10 September 2015.

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

On 6 November 2015, ECHA requested you to provide a proof of payment; the proof of payment was provided on 23 November 2015 and amounted to [redacted] EUR. ECHA has no competence to determine the appropriateness of the "share of the cost", which may eventually be subject to the assessment of a competent national court.

[redacted]

The permission to refer concerns the studies indicated in Annex I to this decision. The statement of reasons of this decision is set out in the Annex II, based on the documentary evidence summarised in Annex III.

In accordance with Articles 63(5) and 77(1) of the BPR, an appeal against this decision may be brought 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.

As a closing remark, ECHA reminds both parties that the outcome of a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would. Accordingly, ECHA strongly encourages the parties to negotiate in order to reach an agreement that will be satisfactory for all.

Yours sincerely,

[redacted]

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

[redacted]

Annex I to decision DSH-63-3-D-[redacted]2015

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

Scope of the dispute:

Access to the complete active substance dossier for [redacted]

Scope of permission to refer:

Pursuant to the combined application of Articles 63(3) and 95(3) of the BPR, the scope of the permission to refer shall apply to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to the active substance [redacted] including any such studies not involving tests on vertebrates.

Title of study
[redacted]

[redacted]

Title of study
[redacted]

[redacted]

Title of study
[redacted]

Title of study
[redacted]

Title of study
[redacted]

[redacted]

Annex II to decision DSH-63-3-D-[redacted]2015

STATEMENT OF REASONS OF THE DECISION OF THE DATA SHARING DISPUTE

Article 63(1) of the BPR requires the Prospective Applicant(s) and the Data Owner(s) to "*make every effort to reach an agreement on the sharing of the results of the tests or studies requested*". If no agreement can be reached, Article 63(3) mandates ECHA on request to "*give the prospective applicant permission to refer to the requested tests or studies on vertebrates, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred*". For submissions relating to the inclusion on the "Article 95"-list, Article 95(3) extends the scope "*to all toxicological, ecotoxicological and environmental fate and behaviour studies*" for active substances included in the Review Programme[1]. On this basis, ECHA conducts an assessment serving to establish whether the parties have fulfilled their legal obligation to make every effort to share the studies and their related costs in a fair, transparent and non-discriminatory way. The assessment is based on the information provided by the Prospective Applicant and the Other Party. An overview can be found in Annex III to this decision.

Under Articles 62 and 63 of the BPR making every effort to reach an agreement means that both parties shall negotiate the sharing of data and related costs as constructively as possible to make sure that the negotiations move forward in a timely manner. Notably, in view of the regulatory deadline relating to Article 95 of the BPR, parties are required to act in a swift manner. Pursuant to Article 95(2) of the BPR, as of 1 September 2015, only biocidal products for which the substance or product supplier is listed on the Article 95 list can be legally made available on the EU market. Closer to the deadline, it was therefore increasingly crucial for those suppliers who wish to stay on the market after 1 September 2015 that the requested information is provided without undue delay and that negotiations move forward as swiftly as possible. Data owners are thus expected to be prepared for requests to share data by prospective applicants, and to readily provide information on the costs for access to data and the underlying calculations including the cost breakdown. This also means that they are expected to respond promptly to prospective applicants' questions and counter-proposals with a view to coming to an agreement as quickly as possible in full respect of the regulatory framework of Article 95 of the BPR.

ECHA notes that the increasing urgency of their request in view of the approaching, at the time of the negotiations, regulatory deadline of Article 95 was repeatedly emphasized by the Prospective Applicant[2] and acknowledged by the Other Party[3]. However, the Other Party's conduct of the negotiations prevented the latter from moving forward constructively, as it would have been required in view of the pressure imposed on the Prospective Applicant to be on the Article 95 list by 1 September 2015.

The Prospective Applicant already on 1 September 2014[4] requested for the first time from the Other Party information on the cost of the Letter of Access (LoA) to the complete active substance dossier for [redacted] as well as the cost breakdown while they confirmed

[1] The work programme established by the Commission under Article 16 of Directive 98/8/EC for the assessment of existing active substances which is continued under Article 89(1) of the BPR, the detailed rules of which are set out in Commission Delegated Regulation (EU) No 1062/2014.
[2] See references no. 24, 26, 33, 37, and 41
[3] See references no. 25 and 36
[4] See reference no.13

their interest in entering into data sharing negotiations for that LoA on 7 November 2014[5]. However, it was only on 1 July 2015[6] when the Other Party provided an indication about the LoA price while they had not provided the requested cost breakdown by the time the dispute claim was lodged, i.e. by 21 August 2015. Receiving the cost breakdown was nevertheless crucial for the Prospective Applicant to exercise their rights and obligations during the data sharing negotiations since determining the fair, transparent and non-discriminatory share of costs is only possible if the incurred costs and the underlying calculation mechanisms have been previously received and can be clearly understood. The cost breakdown of the LoA is the basis of any data sharing negotiation. It enables the parties to find a common understanding and an eventual agreement on the final price for the LoA, and in its absence meaningful negotiations cannot start.

The Other Party expressed their willingness to share the cost breakdown and the list of studies once the Prospective Applicant signed a secrecy agreement[7]. ECHA acknowledges that data owners may have legitimate reasons to request the signing of a confidentiality or non-disclosure agreement during the data sharing negotiations. In case a prospective applicant concedes to that demand, data owners need to respond promptly to the prospective applicant's questions and counter-proposals taking into account any applicable regulatory deadline. While the Prospective Applicant pointed out that a secrecy agreement was not necessary for receiving information from the Other Party on the cost breakdown and the list of studies[8], they displayed willingness to concede to that demand of the Other Party despite their reservations[9]. However, the Other Party's insistence on certain provisions, namely regarding a penalty clause[10], and their failure to timely respond to the Prospective Applicant's legitimate questions and compromise proposals on this matter[11], while the regulatory deadline of Article 95 was fast approaching, prevented the parties from concluding the secrecy agreement and consequently obstructed the Prospective Applicant from receiving the requested information on the list of studies and the cost breakdown.

It was however the Other Party's responsibility to provide upon the Prospective Applicant's repeated requests a complete cost breakdown justifying the LoA cost, and to do so taking into account the imminent, at the time of the negotiations, regulatory deadline of Article 95, i.e. not only timely react to the messages received from the Prospective Applicant, but ensure that the reaction is enabling the negotiations to progress constructively. Thus, when insisting on a secrecy agreement, it would have been the Other Party's responsibility to timely and meaningfully follow up on the Prospective Applicant's counter proposals and to swiftly reply to their arguments and questions.

While it is in the data owners' discretion to agree on a organisation model for data sharing purposes (e.g. data owners conduct the negotiations with the prospective applicant via a representative as an intermediary between the consortium and a prospective applicant[12]), such a choice should not obstruct the legitimate interests of a prospective applicant. The more complex the chosen organisation model is the more efforts are required by the data owners and their representative to be able to progress with the negotiations in a meaningful way.

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[5] See reference no.18
[6] See reference no. 34
[7] See references no. 15, 17, 19, 27, 29, 36 and 38
[8] See reference no. 28
[9] See references no. 31 and 33
[10] See reference no. 32, 34, 38 and 40
[11] See reference no. 31, 33, 35, 37 and 39
[12] See references no. 25, 29 and 36

Thus, by providing an indication of the LoA price at a very late stage of the negotiations and after continuous requests from the Prospective Applicant, by insisting on a secrecy agreement without following up the counter-proposals and by not providing the complete cost breakdown, the Other Party effectively prevented meaningful data sharing negotiations to start and obstructed the Prospective Applicant's opportunity to determine the fair, transparent and non-discriminatory character of the proposed cost compensation. Thereby, the Other Party effectively undermined finding a common understanding on the cost calculation. Based on the above, ECHA concludes that the Prospective Applicant has shown their willingness to engage in meaningful data sharing negotiations by requesting the cost breakdown of the LoA, asking relevant questions and making alternative proposals while highlighting the pressure imposed on them to conclude the negotiations ahead of the regulatory deadline of Article 95. On the other hand, the Other Party did not make every effort to share the data and effectively obstructed meaningful negotiations to start. They did not provide the complete breakdown of the LoA after several months of negotiations and until the dispute claim was lodged, nor did they reply constructively to the alternative proposals put forward by the Prospective Applicant to come to an agreement on the secrecy agreement requested by the Other Party. Despite their display of willingness to take action and their acknowledgement of the urgency of the Prospective Applicant's request to be on the Article 95 list by the deadline of 1 September 2015, they did not provide the information that was necessary for substantive data sharing negotiations to start.

Consequenly, pursuant to Articles 63(3) of the BPR, ECHA grants the Prospective Applicant the permission to refer to certain data submitted by the Other Party.

As a closing remark, ECHA notes that, based on the documentary evidence it received, on the date the dispute wasregistered the Other Party communicated[13] to the Prospective Applicant a proposal to resolve the remaining points of disagreement regarding the secrecy agreement. ECHA therefore strongly encourages the parties to continue their negotiations in order to reach an agreement that will be satisfactory for all while at the same time reminding them that the outcome of a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would.

[13] See reference no. 43

Annex III to decision DSH-63-3-D-[redacted]2015

FACTUAL BACKGROUND REGARDING THE DATA SHARING NEGOTIATIONS

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

Ref. no.	Date	Content	Remark
1	31/10/2013	The Prospective Applicant initiated the negotiations, expressing their interest in membership of the "[Consortium]".	
2	31/10/2013	The Other Party confirmed that the group was open for new members and proposed to further discuss membership during a phone call.	
3	31/10/2013	Phone call arrangements between the Prospective Applicant and the Other Party	
4	31/10/2013		
5	31/10/2013		
6	05/11/2013		
7	06/11/2013		Only provided by the Other Party
8	19/11/2013	Following up on the phone call, the Prospective Applicant requested "*feedback from the [Consortium] group about our admission request*".	
9	12/12/2013	The Other Party informed of a change of the responsible contact person and indicated that they would "*soon send [...] more information*".	
10	12/12/2013	The Prospective Applicant confirmed that they were waiting for further information.	Only provided by the Other Party
11	28/01/2014	The Prospective Applicant requested to "*follow up to [their] request as soon as possible*".	
12	30/01/2014	The Other Party informed that the Prospective Applicant's interest in Consortium group membership was discussed at the Consortium's November meeting and reconfirmed that new members would be accepted. They further informed that full membership would include "*full co-ownership rights on the studies, the jointly financed chapters of IUCLID and the [redacted] dossier*" for an "*entrance fee*" of [redacted]EUR, plus yearly Consortium and [redacted] membership payments. Further, the Other Party explained the admission process for new members, and informed that the group's "*Operating Rules*" were currently under revision.	
13	01/09/2014	The Prospective Applicant asked the Other Party to provide "*the full list of studies which are part of the dossier*", further justification of the[redacted] EUR membership fee and a cost-breakdown "*for each specific study*".	

Ref. no.	Date	Content	Remark
		Further, they requested clarification regarding the Consortium group membership, *inter alia* regarding annual costs, mandatory [redacted] membership, number of group members, etc. Finally, they asked for the cost of the LoA "*without joining the [Consortium] as a full member*" as well as for the cost-breakdown "for each individual study, so that [they] can make a fully informed decision".	
14	16/09/2014	The Prospective Applicant requested a confirmation of receipt of their message of 1 September 2014 as well as an answer to their questions raised in that message.	
15	01/10/2014	The Other Party explained the Consortium entrance fees, highlighting that the basic principle was equal participation of all members in "*all costs generated since the start*" of the group. They further also explained the annual costs, addressed the question regarding the [redacted] membership costs, and informed that at that point in time the Consortium had 13 members. In addition, they informed that the Operating Rules were not finalised yet and therefore could not be shared. They then explained that the LoA costs for Art.95 "*are not available yet*" while "*legal and financial details of data sharing*" were currently being finalised. However, they indicated that the costs for a LoA to the full dossier would be "*in the range of the membership entrance fee*". Finally, they informed that a secrecy agreement would be required "*in order to start negotiations*".	
16	15/10/2014	The Prospective Applicant repeated and specified their request for the list of studies including a cost-breakdown, and asked for clarifications regarding a number of cost factors mentioned by the Other Party: the risk premium, investment premium, and interest adjustment. Regarding the LoA, they requested information on the calculation method and whether co-ownership of the data would be included in either Consortium membership or the LoA.	
17	04/11/2014	In response to the request to provide the list of studies and a cost-breakdown, the Other Party informed that this would require prior signature of the secrecy agreement. Further, they explained that the risk premium "*applies to the dossier costs to cover the risks taken by [Consortium] members to build the dossier*", that the investment premium would apply to all costs, and that interest was applied "*since the start of the group*" (2002). Regarding the LoA costs, they informed that they were currently being finalised and would be "*available soon*". Finally, they explained that Consortium membership included co-ownership of the data, while the LoA would only cover the permission to refer to the data and to use it for Art. 95(4) sublicensing purposes.	
18	07/11/2014	The Prospective Applicant returned the confidentiality agreement with a number of changes, *inter alia* to adapt the purpose to buying a LoA (instead of Consortium membership) by deleting the wording on deposit	

Ref. no.	Date	Content	Remark
		and chemical similarity.	
19	19/11/2014	The Other Party provided a new draft confidentiality agreement tailored to buying a LoA, from which the clauses on a deposit had been deleted following the Prospective Applicant's earlier comments, and explaining that the version previously shared with the Prospective Applicant was designed for Consortium membership negotiations. They further informed that the final cost for the LoA were not finalised yet.	
20	09/12/2014	The Prospective Applicant provided comments to the latest draft secrecy agreement by deleting references regarding a deposit and chemical similarity, and including clarification that confidentiality would not prevent them from informing the authorities about the negotiations. Further, they requested clarification regarding the Other Party's statement that legal and financial details of the LoA would still be pending finalisation, expressing they "*thought that the cost of the studies would be a fixed and known amount (based on documentary evidence)*".	
21	09/12/2014	The Prospective Applicant provided the correct version of the commented secrecy agreement, stating that the version provided earlier was sent by mistake.	
22	18/12/2014	The Other Party informed they would only be able to come back to the Prospective Applicant with more information "*in early January*", and explained that the finalisation of the financial details of the LoA referred to ensuring consistency with the requirements under the BPR.	
23	19/12/2014	The Prospective Applicant agreed to wait for the requested information until January.	Only provided by the Other Party
24	14/01/2015	The Prospective Applicant reminded of their earlier requests regarding the LoA costs, the cost calculation and cost breakdown, as well as their comments to the draft secrecy agreement. They further asked how many parties were involved in the cost sharing and whether a refund mechanism was foreseen in case further parties were seeking access to the data. Finally, they underlined that a prompt answer would be required "*for both regulatory and commercial reasons*".	
25	19/01/2015	Regarding the secrecy agreement, the Other Party requested a justification why the Prospective Applicant had removed the wording on chemical similarity, and informed that this change required consultation with the Consortium members as it was "*a critical point of this agreement*". In response to the increasing urgency on the side of the Prospective Applicant, they explained that "*as [the Consortium] is made of several companies, we need to make sure that all [Consortium] members agree to the proposed data sharing strategy*", indicating the possibility of "*more information towards the end of*	

Ref. no.	Date	Content	Remark
		February".	
26	07/05/2015	The Prospective Applicant informed that they had submitted an inquiry to ECHA, as they still had not received a reply from the Other Party regarding the LoA cost, calculation mechanism and cost-breakdown, underlining again the "*regulatory timeframe*".	
27	08/05/2015	The Other Party stated that pending an answer to their request to "*justify [the Prospective Applicant's] request to remove the chemical similarity clause*", they had "*believed that [the Prospective Applicant] were no longer interested in pursuing this route for data access*". However, upon signature of the secrecy agreement, they would be available to continue the negotiations.	
28	11/05/2015	The Prospective Applicant replied that neither chemical similarity nor a secrecy agreement were required under the BPR before the start of data sharing negotiations or before the list of studies could be provided.	
29	13/05/2015	The Other Party informed that the Consortium members had agreed to include chemical similarity into the secrecy agreement "*in order to ensure awareness*" of this requirement during product authorisation, underlining that the proposed wording would not require chemical similarity before the conclusion of a data sharing agreement. Regarding the list of studies, they informed that the Consortium would insist on concluding a secrecy agreement before sharing "*crucial data for [the Consortium], such as the list of studies or the detailed costs linked to the data sharing discussions*". In case the Prospective Applicant did not agree to sign the secrecy agreement including the wording on chemical similarity, the Other Party would need to request the "*14 [Consortium] members [...] to accept deviating from the standard procedure for data sharing*", which "*may slightly delay the process*".	
30	01/06/2015	The Other Party requested if the Prospective Applicant had any feedback regarding their last message.	
31	03/06/2015	The Prospective Applicant addressed the Other Party's comments regarding chemical similarity by suggesting to replace the chemical similarity relevant parts from the secrecy agreement with clarification that "*chemical similarity is not a condition for concluding a data sharing agreement with [the Consortium]*",. In Prospective Applicant's view, this would not require the Other Party to seek approval for these changes from the Consortium members, since such addition "*simply reflects the content of [Other Party's] email and the legal context of the negotiations*". Further, they disagreed with the [redacted] EUR penalty clause foreseen in cases of breach of confidentiality, as well as with the Other Party's approach that the list of studies was "*crucial confidential information per se*", highlighting that neither the list nor the cost of studies should be confidential as "*there is an obligation under the BPR on the part of the data owners to communicate the cost of the studies with a related breakdown*".	

Ref. no.	Date	Content	Remark
		They announced their willingness to sign the secrecy agreement "*without hidden clauses such as financial deposits, chemical similarity and penalty clauses*", and confirmed they would immediately sign such a revised version, in order to then receive "*immediately thereafter*" the LoA offer including the cost breakdown. Finally, they informed that they were considering setting up a "*small consortium to divide costs with other SMEs*", and asked how the the Consortium would deal with a request to include two additional companies into the request for access to the studies.	
32	05/06/2015	With this email, the Other Party provided a revised secrecy agreement, accepting to remove the deposit clause, adding clause acknowledging that chemical similarity it is not a legal requirement, but keeping the liability clause. Regarding potential additional parties (consortium of SMEs) seeking access to the data, they stated that data sharing would need to be agreed on individual basis.	
33	26/06/2015	The Prospective Applicant agreed to the revised secrecy agreement, except for the [redacted] EUR penalty clause which they suggested to be subject to a court judgement to avoid "*an automatic penalty for any disclosure, irrespective of whether damages have actually been incurred*". They also repeated their request for the LoA cost and the cost-breakdown, underlining that they "*cannot accept to continue negotiating over a secrecy agreement without knowing the amount [the Other Party is] are asking [the Prospective Applicant] to pay for a LoA*" and insisting that "*the initial price offer for a LoA should be communicated upfront without any secrecy*". Further, they asked whether it might be possible to purchase "*an 'over-the-counter'/fast track LoA at a fixed price (i.e. without negotiation)*". Finally, they announced they might need to refer the matter to ECHA as they could not proceed without a price offer and as "time is pressing" due to the Article 95 deadline of 1 September 2015.	
34	01/07/2015	In response to the Prospective Applicant's request regarding the penalty clause, the Other Party requested the Prospective Applicant to propose a new wording which the Consortium members could discuss at their conference call the following week. Regarding the LoA costs, they informed that the price is "*at the moment set around* [redacted] *EUR*", which might be "*adapted downwards in the future*" if additional parties sought access to the data.	
35	14/07/2015	The Prospective Applicant suggested two changes to the secrecy agreement: firstly, regarding confidentiality of information already in possession of the receiving party; and secondly, a wording allowing national courts or an arbitration body to establish whether a breach of confidentiality has caused tangible damage. Further, they stated that the suggested LoA price of [redacted] EUR was "*extremely high considering that the*	

Ref. no.	Date	Content	Remark
		LoA [...]does not grant co-ownership rights" and therefore asked to grant a 50% discount, and repeated their request for a detailed cost-breakdown "*to better assess your price basis*". They also asked whether any use limitations were foreseen in the data sharing agreement which might justify further discounts. Finally, they repeated their question concerning a LoA without further detailed data sharing negotiations granting only very limited rights in exchange for a significantly discounted price.	
36	15/07/2015	The Other Party stressed that they understood the regulatory urgency, but informed the telephone conference with the Consortium members had passed already and therefore the changes proposed by the Prospective Applicant would need to be sent for "*electronic approval*" which "*requires some time*", highlighting that "*[the Consortium] members have invested time and resources to prepare data sharing rules [...] which are fair, reasonable and transparent*" and that "*[s]everal third parties deemed these terms acceptable*" They explained that a cost-breakdown would be shared once the secrecy agreement is signed. They informed that a 50% reduction had already been included to reflect that the LoA doesn't grant co-ownership rights, but that no discounted LoA with sped-up negotiations granting limited rights was available. However, they outlined they could issue the normal LoA within shortest delays once the Prospective Applicant accepted their terms. Finally, they asked to "*confirm that [the Prospective Applicant] is willing to bear the implications of a delay for signature of the secrecy agreement*", and announced they would be on holiday till end of July.	
37	17/07/2015	Regarding the disagreed parts of the secrecy agreement, the Prospective Applicant suggested to remove them "*as they are not pertinent*". As the Other Party did not offer the mentioned discounted LoA without full data sharing negotiations, they agreed to the standard negotiation route, repeating their request for a "*final cost calculation including a breakdown of the costs, the total number of parties with access rights, the basis for the calculation and data compensation, any use restrictions [...] and a draft data sharing contract with a related LoA under Article 95*". With reference to the Other Party's earlier statement that the LoA costs were still being calculated, they stated that "*with less than two months before the 1 September deadline we find this unacceptable*". They further expressed their concern that the Other Party's absence due to vacations will cause that "*there will be no time left for negotiations*" and therefore informed that "*any further delay in the process will inevitably impact on our ability to complete the negotiation on time for the 1 September*" and would force them to refer the matter to ECHA.	
38	17/07/2015	The Other Party informed that the Consortium members had developed "*data sharing documents and cost proposal which are fair, reasonable and transparent*", and that "*the costs of [the Consortium] checking [...]*	

Ref. no.	Date	Content	Remark
		legal implications" of changing the secrecy agreement should be taken by the Prospective Applicant and would in addition "*create an inevitable time delay*". The Other Party further informed that the cost breakdown had been finalised already earlier and would be shared following signature of the secrecy agreement, explaining that signing the secrecy agreement would be required as the first step of the data sharing procedure before seeing "*crucial data for [the Consortium], such as the list of studies or the detailed costs*".	
39	20/07/2015	The Prospective Applicant accused the Other Party of imposing a secrecy agreement which "*is not in line with the template secrecy agreement available in the EU guidelines on data sharing*", informing that they "*cannot accept [The Other Party's] 'take it or leave it' approach*" nor the proposal to charge them for their request to remove clauses. If no agreement on the modifications could be found, they proposed to use the template recommended by ECHA /Commission instead and asked the Other Party to provide them with a signed copy "*without any further delay*", adding that "*the only cause for delay*" was the Other Party's insistence on additional non-standard clauses. Regarding the LoA costs and the cost-breakdown, they highlighted that so far they had only received "*an unsupported total figure of* [redacted] *EUR*", and that none of their requests for further information had been answered. On this basis, they concluded that they were "*not in a position to comment on that figure*", but that it seemed "*excessive considering the standard cost to repeat the studies, the total number of companies involved and the fact [of] only seeking a LoA under Art. 95 BPR (no co-ownership)*" . Further, they highlighted that it was the Other Party who opted for in-depth data sharing negotiations, which consequently would require the parties to enter into detailed discussions – which would then require them to receive a cost-breakdown to be able to assess the offer. Finally, they quoted ECHA's Practical Guide on Data Sharing, pointing out that a cost-breakdown needed to be provided without secrecy agreement. Therefore, "*the delay in negotiations can only be attributed to the [Consortium]*", and any further delay would lead to them referring the matter to ECHA.	
40	31/07/2015	The Other Party noted that the Prospective Applicant was "*not willing to change its position regarding the penalty clause of the secrecy agreement or agree to the compromise proposed by the [Consortium] members to support the costs of [the Consortium] checking the legal implications of changing the template agreement*", and announced they would now need to first consult internally with the Consortium members before making any "*alternative compromise*".	
41	20/08/2015	In their message, the Prospective Applicant concluded that the Other Party was not willing to provide a cost-breakdown before the signature of the secrecy agreement despite the "*EU Guidelines on data sharing*"	

Ref. no.	Date	Content	Remark
		outlining that "*a breakdown of the costs must be provided to the prospective applicants irrespective of a secrecy agreement*". Therefore, they concluded they were "*still far from an agreement*" and "*unable to progress matters into a meaningful way*" and hence, also in light of the imminent deadline of 1 September, they would refer the matter to ECHA.	
42	21/08/2015	The Prospective Applicant requested confirmation of receipt of the previous message.	Only provided by the Other Party
43	21/08/2015	The Other Party's legal counsel contacted the Prospective Applicant and provided a revised secrecy agreement [secrecy agreement not attached]	