

[REDACTED]  
14 November 2016

The Prospective Applicant:

[REDACTED]

Copy to the Other Party:

[REDACTED]

Represented by:

[REDACTED]

**Sent via encrypted email and registered mail**

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 63(3) of the Biocidal Products Regulation (EU) No 528/2012 ('BPR'),

**ECHA grants you permission to refer to the data listed in Annex I.**

### **2. Procedural history**

On 29 August 2016, ECHA registered the claim that you (the 'Prospective Applicant') submitted on 26 August 2016 concerning the failure to reach an agreement on data sharing with [REDACTED] (the 'Other Party') as well as the related documentary

evidence<sup>1</sup> to ECHA. Data sharing had been sought for an application to be included on the Article 95 list.<sup>2</sup> 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 14 September 2016.

### 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>.

### 4. Advice and further observations

ECHA reminds both parties that despite of the present decision they are still free 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.

Yours sincerely,

Christel Schilliger-Musset<sup>3</sup>

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

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<sup>1</sup> The documentary evidence submitted by the Prospective Applicant also includes a proof of payment of █████ EUR to the benefit of the Other Party, dated 26 May 2016 (see document reference no. 137).

<sup>2</sup> Under Article 95 of the BPR, ECHA is tasked with publishing and updating regularly a list of substance and product suppliers that have made a submission for a relevant substance as required by this provision. As of 1 September 2015, only biocidal products consisting of, containing or generating a relevant substance for which either the substance or product supplier is included on the Article 95 list can be made available on the market.

<sup>3</sup> 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.

**Annex I to decision [REDACTED]**
**LIST OF STUDIES SUBJECT TO THE DISPUTE, TO WHICH ECHA GRANTS THE PERMISSION TO REFER**

**Scope of permission to refer:** Pursuant to the combined application of Articles 63(3) and 95(3) of the BPR, for substances in the Review Programme<sup>4</sup> the scope of the permission to refer shall apply to all toxicological, ecotoxicological and environmental fate and behaviour studies, including any such studies not involving tests on vertebrates. The requested studies fall under the extended scope of the right to refer in accordance with Articles 63(3) and 95(3) of the BPR. Thus, the scope of the permission to refer includes the following studies:

Author	Title / Year
[REDACTED]	[REDACTED]

<sup>4</sup> 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.

Author	Title / Year
[REDACTED]	[REDACTED]

Author	Title / Year
[REDACTED]	[REDACTED]

Author	Title / Year
[REDACTED]	[REDACTED]

Author	Title / Year
[REDACTED]	[REDACTED]

**Annex II to decision** [REDACTED]**STATEMENT OF REASONS OF THE ASSESSMENT OF THE DATA SHARING DISPUTE**

Article 63(1) of the BPR requires prospective applicant(s) and data owner(s) to *'make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant'*. If no agreement can be reached, Article 63(3) of the BPR 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'*. Accordingly, if ECHA finds that the prospective applicant complied with their obligation to make every effort to reach a fair, transparent and non-discriminatory agreement and paid the data owner a share of the costs incurred, the Agency shall grant the prospective applicant the permission to refer to the requested data. For submissions of alternative suppliers relating to their inclusion on the Article 95 list, Article 95(3) of the BPR extends the scope of the right to refer under Article 63(3) of the BPR for active substances included in the Review Programme<sup>5</sup> *'to all toxicological, ecotoxicological and environmental fate and behaviour studies [...] including any such studies not involving tests on vertebrates'*.

Following the lodging of the dispute claim by the Prospective Applicant, ECHA conducted an assessment serving to establish whether the parties have fulfilled their legal obligation to make every effort to share the studies and their related costs 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.

**Factual background**

In the case at hand, the Prospective Applicant initiated the data sharing discussions before the entry into operation of the BPR.<sup>6</sup>

Negotiations intensified however only after the entry into operation of the BPR, with a first meeting between the Parties taking place on 2 October 2013 in which they agreed to sign an Every Effort and Secrecy Agreement ('EESA') before continuing with their further data sharing discussions.<sup>7</sup> Between October 2013 and September 2014, the exchanges between the Parties related to the EESA.<sup>8</sup>

In accordance with the EESA, the Parties then agreed on commissioning a laboratory to perform a chemical similarity assessment between the two active substance sources.<sup>9</sup> The contractual arrangements with the laboratory lasted until the beginning of September 2015.

With their email of 28 August 2015, the Prospective Applicant expressed their concern for the delays related to the arrangements of the chemical similarity assessment. For that reason, the Prospective Applicant noted that the Parties need to *'move forward on data sharing in parallel'* and requested the list of studies and the cost for the letter of access

<sup>5</sup> 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.

<sup>6</sup> See document references no. 1 – 6

<sup>7</sup> See document references no. 7 – 13

<sup>8</sup> See document references no. 14 – 36

<sup>9</sup> See document references no. 37 – 101, 103 – 106, 116.

(‘LoA’).<sup>10</sup> In their reply, the Other Party indicated that according to the EESA, *‘[n]o information will be disclosed [...], unless and until Every Effort has been made by the Prospective Applicant to establish Chemical similarity’*.<sup>11</sup> The Prospective Applicant answered that they *‘do not see any issue in starting the data sharing discussion from now to facilitate the progress of [their] request’*. They also noted that in their understanding the EESA *‘does not say that no information will be disclosed until Chemical similarity has been established’*.<sup>12</sup>

Despite their earlier unwillingness to discuss data sharing prior to the establishment of chemical similarity, on 18 September 2015, the Other Party provided the Prospective Applicant with a list of studies subject to data sharing as well as a quotation for the LoA.<sup>13</sup> On the same day, the Prospective Applicant informed the Other Party about the studies held by them.<sup>14</sup> The Prospective Applicant also made a counter-offer for the LoA and specified the list of studies for which they wanted to negotiate data sharing.<sup>15</sup>

On 18 November 2015,<sup>16</sup> the laboratory, which had been contracted to perform the chemical similarity check, informed the Parties that the result was *‘inconclusive’*. It also highlighted that *‘as a chemical similarity check is comparable to a Tier I technical equivalence assessment, the reference source and alternative source may be determined to be technically equivalent following a Tier II assessment by ECHA however this falls outside the scope of this chemical similarity check.’*

On the same day,<sup>17</sup> the Other Party informed the Prospective Applicant that the clause of the EESA would now be applicable according to which *‘When, irrespective of the will of the Parties, no chemical similarity can be established between the specifications by the appointed consultant, the Parties will have to stop negotiating a Data Sharing Agreement’*. In their reply,<sup>18</sup> the Prospective Applicant argued that the chemical similarity assessment was *‘inconclusive, which does not mean that no chemical similarity can be established’*. They further noted that they had fulfilled the EESA requirement to make every effort to establish chemical similarity. They therefore requested *‘that the data sharing discussions [...] will be continued without undue delay’*. The Prospective Applicant argued that the *‘primary objective’* of the EESA was to agree on data sharing rather than to establish chemical similarity, and informed the Other Party that they would ask ECHA for a chemical similarity assessment too.<sup>19</sup> They also announced that they would file a data sharing dispute with ECHA should the Other Party refuse to continue the data sharing negotiations.<sup>20</sup>

The Prospective Applicant repeated several times their request to continue negotiations and to receive a reply to the counter-offer they have made for the LoA on 18 September 2015.<sup>21</sup> On 10 August 2016, they also informed the Other Party about the result of ECHA’s chemical

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<sup>10</sup> See document reference no. 102

<sup>11</sup> See document reference no. 107

<sup>12</sup> See document reference no. 108

<sup>13</sup> See document reference no. 117

<sup>14</sup> See document reference no. 118

<sup>15</sup> See document reference no. 122

<sup>16</sup> See document reference no. 129

<sup>17</sup> See document reference no. 130

<sup>18</sup> See document reference no. 131

<sup>19</sup> See document reference no. 133

<sup>20</sup> See document references no. 133, 135.

<sup>21</sup> See document references no. 131, 133, 135, 138 and 142

similarity assessment. The result showed that the Agency could not confirm that the two sources are chemically similar underlining however the following:

*'At this stage of the review of the active substance, the reference source information for the active substance [...] has not yet been discussed in the working groups of the Biocidal Products Committee. These steps are necessary for setting the reference source and reference specifications of the active substance and its eventual approval under Article 9(1) of the BPR. Therefore, the outcome of the chemical similarity check is only in relation to the information which is available on the reference source at the time of this assessment. [...T]he reference source information which has been used for the present chemical similarity check may be different from the information which will be available for the final approved reference source after approval of the active substance.'*<sup>22</sup>

The Prospective Applicant asked the Other Party 'to waive [their] insistence' on establishing chemical similarity as a pre-condition for continuing the negotiations<sup>23</sup>, underlining that 'the risk of there not being technical equivalence at the product authorisation stage [...] is upon [the Prospective Applicant]'.<sup>24</sup> They emphasised that to access the market they need to be included on the Article 95 list, and therefore they 'simply cannot bear the prolonged negative market impacts' of not having access to the Other Party's data<sup>25</sup>.

From their side, the Other Party argued repeatedly that in their view according to the EESA negotiations would need to stop because of the inconclusive chemical similarity assessment.<sup>26</sup> They claimed that the Prospective Applicant 'freely entered into [the] commitment' to stop negotiations if chemical similarity cannot be established by the agreed laboratory;<sup>27</sup> and that lodging a data sharing dispute would therefore be 'premature'.<sup>28</sup> Further, they stated that they would continue negotiations on data and cost sharing once the chemical similarity would be established.<sup>29</sup> They also expressed their willingness to 'explore with [the Prospective Applicant] how [the Other Party] can help in the establishment of chemical similarity'<sup>30</sup>. However, ECHA has not received any documentary evidence that shows that the Other Party followed up on their expressed interest in advancing the chemical similarity discussions.

## Assessment

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 their related costs as constructively as possible to make sure that the negotiations move forward in a timely manner. Prospective applicants and data owners thus need to explore different options and make alternative proposals to unblock the negotiations in case of disagreements. Making every effort also means that the parties must continue their efforts to reach an agreement and only use the dispute mechanism under the BPR as a measure of last resort, when all other options have been exhausted.

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<sup>22</sup> See document reference no. 138 (emphasis added by the Prospective Applicant)

<sup>23</sup> *Ibid.*

<sup>24</sup> See document reference no. 142

<sup>25</sup> See document reference no. 142

<sup>26</sup> See document references no. 132, 134, 136 and 141

<sup>27</sup> See document reference no. 136

<sup>28</sup> See document reference no. 141

<sup>29</sup> See document references no. 134, 136 and 141

<sup>30</sup> See document reference no. 136

In line with the principle of contractual freedom, the parties are free to insert a clause in their data sharing agreement relating to the chemical similarity check of their active substance sources.<sup>31</sup> The parties may thus contractually agree making their data sharing agreement conditional upon the performance of the chemical similarity check.

Further, the chemical similarity assessment that is carried out by ECHA is performed solely on the substance identity and chemical composition of the active substance of the applicant, with the aim of establishing its similarity with the chemical composition of the substance, which is currently under evaluation in the review programme.<sup>32</sup> Since the chemical similarity assessment is performed before the approval of the active substance, thus at a time when the official reference source of the active substance has not yet been established, its result may not be conclusive. Chemical similarity check may also be performed by a third party following the same criteria.

In the case at hand, based on the result of the chemical similarity check performed by the laboratory, it was not possible to determine whether the active substances of the parties were chemically similar. The laboratory however left open the possibility of the technical equivalence between the two active substance sources following the approval of the active substance. Similarly, ECHA explained that the negative result of the chemical similarity assessment it had performed on the parties' active substances was without prejudice to their eventual technical equivalence once the active substance is approved and the final reference source is established.

Due to the uncertainty surrounding the matter of chemical similarity between the parties' active substances, the parties had to make efforts to explore in a constructive manner the options that were available to allow their negotiations to progress and the Prospective Applicant to fulfil its regulatory obligation under Article 95 of the BPR.

On its side, following the Other Party's statement that the data sharing negotiations should stop due to the inconclusive result of the chemical similarity check performed by the laboratory, the Prospective Applicant made efforts to prevent the negotiations from reaching an impasse. They informed the Other Party that they would also avail themselves of the service provided by ECHA for the establishment of the chemical similarity between the parties' active substances. This demonstrates that the Prospective Applicant took steps to explore additional options to help the parties progress with their negotiations with regard to the chemical similarity of their active substance sources. In doing so, the Prospective Applicant exercised care and diligence, which constituted an effort within the meaning of Article 63 of the BPR.

In addition, during the same time-period, the Prospective Applicant repeatedly requested the Other Party to continue their earlier negotiations on the list of studies and the cost for the LoA while the chemical similarity issue was pending. Indeed, between August and October 2015, the parties had already exchanged certain information on the list of studies and the LoA while awaiting the result of the chemical similarity assessment by the laboratory. The parties could have thus used effectively the time after the communication of the laboratory's result to follow up on these earlier exchanges while exploring the options available with regard to the chemical similarity issue. However, the Other Party refused to continue the discussions on the sharing of the requested data and its cost while the chemical similarity between the two active substance sources had not been established. By refusing to pursue the data sharing negotiations, the Other Party demonstrated a failure to make every effort.

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<sup>31</sup> See also at paragraph 74 of the decision of ECHA's Board of Appeal in the appeal case [REDACTED]

<sup>32</sup> See also ECHA's explanations in the communication to the Prospective Applicant, document reference no. 138.

Moreover, the Other Party failed to make constructive efforts to advance the discussions on establishing chemical similarity between the parties' active substances despite their expression of willingness to do so. While the Prospective Applicant continued their efforts in this regard by using ECHA's related service, the Other Party did not make any other concrete proposal or offered assistance to progress these negotiations.

### **Conclusion**

Based on the above, ECHA concludes that the Other Party failed to comply with their obligation to make every effort to reach an agreement by preventing the negotiations from progressing. On the other hand, the Prospective Applicant made every effort to continue the data sharing negotiations and used the data sharing dispute procedure as a last resort.

ECHA therefore grants the Prospective Applicant the permission to refer to the data listed in Annex I.

**Annex III to decision**
**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	Comment
1.	10/10/2012	The Claimant announces their interest to discuss 'a possible cooperation' for 'supporting [the substance] under the BPR'.	Only provided by the Other Party
2.	02/11/2012	The Claimant requests data sharing for 'all toxicological and eco toxicological studies including any toxicological and eco toxicological studies not involving tests on vertebrate animals' in accordance with Article 95 BPR. They ask for 'a Letter of Access to your BPD dossier on [the substance] for [redacted] and propose to 'combine our resources in the defence of this active substance'.	
3.	12/11/2012	The Other Party replies, stating that they wish to clarify with the European Commission the scope of mandatory data sharing.	
4.	26/11/2012	The Claimant requests to negotiate 'sharing of the toxicological and eco toxicological studies against fair compensation'. Further, they suggest a meeting or conference call and write they intend to submit their dossier in September 2013.	
5.	10/05/2013	The Claimant asks whether the Other Party is available for a conference call.	
6.	13/05/2013	The Other Party states they are available to discuss data sharing '[o]nce the data sharing requirements of the BPR are clear'.	
7.	16/09/2013	The Other Party states they are 'prepared to meet [their] obligations under Articles 62, 63 and 95' and asks whether the Claimant is interested in further negotiations.	
8.	18/09/2013	The Claimant confirms their interest and suggests to meet.	
9.	18/09/2013		
10.	18/09/2013		
11.	19/09/2013	Meeting arrangements for 2 October 2013 in Brussels.	

12.	24/09/2013		
13.	11/10/2013	The Claimant sends the draft minutes of their meeting, addressing <i>inter alia</i> : - Classification of the substance and mutual access to related studies - The Claimant's interest in 'a LoA to the complete BPR dossiers for [REDACTED] and possibly [REDACTED]'. The Claimant prefers access to the whole dossier covering also to environmental fate data, while the Other Party has some reservations. - Preparation of a secrecy agreement by the Other Party	
14.	11/10/2013	The Other Party comments on the draft minutes, clarifying that they might give the Claimant access 'for review purposes, to the studies concerning the [REDACTED] [REDACTED]'. [REDACTED]	Commented minutes provided to ECHA
15.	13/10/2013	The Claimant agrees to the comments made by the Other Party.	Only provided by the Other Party.
16.	08/11/2013	The Claimant asks about progress with the secrecy agreement.	Only provided by the Other Party.
17.	08/11/2013	The Other Party informs they will use the draft secrecy agreement from another substance as the basis and 'are working on this approach'.	Only provided by the Other Party.
18.	25/11/2013	The Other Party informs that the discussions on the secrecy agreement for the other substance are progressing.	Only provided by the Other Party.
19.	26/11/2015	The Claimant thanks for the update.	Only provided by the Other Party.
20.	28/01/2014	The Other Party informs that they are 'close to agreement' concerning the secrecy agreement for another substance and will use this for the substance at hand, too.	
21.	28/01/2014	The Claimant thanks for the information.	Only provided by the Other Party.
22.	11/06/2014	The Claimant provides an amended secrecy agreement based on the agreement found for the other substance, and asks the Other Party to 'review/update and confirm' the draft.	Draft provided to ECHA
23.	11/06/2014		
24.	11/06/2014	Agreement on and signature of 'Every Effort and Secrecy Agreement under the Biocidal Products Regulation [...]'	Only provided by the Other Party.
25.	02/07/2014		

26.	03/07/2014		
27.	03/07/2014		
28.	22/07/2014		
29.	29/07/2014		Only provided by the Other Party.
30.	05/08/2014		
31.	14/08/2014		
32.	15/08/2014		Only provided by the Other Party.
33.	15/08/2014		Only provided by the Other Party.
34.	19/08/2014		
35.	25/08/2014		Signed agreement provided to ECHA
36.	16/09/2014		Only provided by the Other Party.
37.	16/09/2014	The Other Party informed they have asked '5 different consultancies for the chemical similarity work' and asked for quotations. They ask how to share the costs between the companies and for the 2 substances (including the one subject to the dispute).	
38.	25/09/2014	The Other Party provides a summary of the received price quotations and proposes a phone call to discuss further.	Wrong summary of price quotations provided to ECHA only by the Other Party.
39.	25/09/2014	The Other Party provides a corrected summary.	Corrected summary of price quotations provided to ECHA.
40.	08/01/2015		Only provided by the Claimant
41.	16/01/2015	Meeting arrangements for 23 February 2015 in [REDACTED]	Only provided by the Claimant
42.	18/01/2015		Only provided by the Claimant
43.	22/01/2015		Only provided by the

			Claimant
44.	26/01/2015		
45.	27/01/2015		
46.	27/01/2015		
47.	06/02/2015		
48.	10/02/2015		Only provided by the Other Party.
49.	27/02/2015	The Claimant sends the draft minutes of the meeting of 23 February 2015, and asks the Other Party to review and confirm them. Issues discussed cover: - further steps to establish chemical similarity - subsequent provision of list of studies and their prices by the Other Party - hazard data	Draft minutes only provided by the Other Party.
50.	04/03/2015	The Other Party provides the amended minutes.	Commented minutes provided to ECHA.
51.	11/03/2015	The Claimant agrees to the commented minutes and also agrees to one of the proposed laboratories for the chemical similarity assessment.	Only provided by the Other Party.
52.	13/03/2015		Only provided by the Other Party.
53.	18/03/2015		
54.	24/03/2015		
55.	30/03/2015		
56.	30/03/2015		
57.	02/04/2015		
58.	05/04/2015	Agreement and signature of chemical similarity contract with laboratory, including confidentiality agreement with all three parties <sup>33</sup>	Only provided by the Other Party.
59.	07/04/2015		
60.	14/04/2015		
61.	17/04/2015		
62.	17/04/2015		
63.	17/04/2015		
64.	24/04/2015		

<sup>33</sup> Note that this includes also messages sent by the laboratory and not by either of the parties of the dispute, as well as attachments e.g. draft contracts and price quotes

65.	27/04/2015		
66.	28/04/2015		Only provided by the Other Party.
67.	03/05/2015		
68.	05/05/2015		
69.	05/05/2015		
70.	13/05/2015		
71.	20/05/2015		
72.	22/05/2015		
73.	22/05/2015		
74.	22/05/2015		Only provided by the Other Party.
75.	26/05/2015		
76.	04/06/2015		Only provided by the Other Party.
77.	04/06/2015		Only provided by the Other Party.
78.	16/06/2015		Only provided by the Other Party.
79.	17/06/2015		Only provided by the Claimant.
80.	01/07/2015		Only provided by the Other Party.
81.	02/07/2015		Only provided by the Other Party.
82.	03/07/2015		
83.	06/07/2015		
84.	14/07/2015		
85.	21/07/2015		
86.	21/07/2015		
87.	27/07/2015		
88.	27/07/2015		
89.	30/07/2015		

90.	03/08/2015		Signed agreement provided to ECHA
91.	03/08/2015		Draft chemical similarity contract and price quote provided to ECHA
92.	04/08/2015		
93.	12/08/2015		Only provided by the Other Party.
94.	13/08/2015		Only provided by the Other Party.
95.	19/08/2015		Amended contract provided to ECHA
96.	19/08/2015		
97.	20/08/2015		
98.	20/08/2015		
99.	20/08/2015		Only provided by the Other Party.
100.	25/08/2015		
101.	27/08/2015		
102.	28/08/2015	The Claimant writes they are <i>'concerned by the delays accumulated for the establishment of chemical similarity'</i> and that they would like to <i>'move forward on the data sharing in parallel, and receive a quotation from [the Other Party] for mandatory data within a reasonable time frame'</i> . They ask for the <i>'list of studies which are subject to mandatory data sharing'</i> , the price quotation for a Letter of Access (LoA) and a <i>'summary of the available data for the critical endpoints [REDACTED]'</i> by 11 September 2015.	Attachment (letter) provided to ECHA
103.	28/08/2015		
104.	01/09/2015	Agreement and signature of chemical similarity contract with laboratory, including confidentiality agreement with all three parties	Only provided by the Other Party.
105.	03/09/2015		
106.	03/09/2015		
107.	03/09/2015	The Other Party agrees to a meeting and announces to propose possible dates. They underline that the every effort and secrecy agreement (EESA) states that	

		<i>'[n]o information will be disclosed [...], unless and until Every Effort has been made by the Prospective Applicant to establish Chemical similarity'.</i>	
108.	08/09/2015	<p>The Claimant announces they will indicate suitable meeting dates. They also send a letter repeating their request for the list of studies and the LoA quote.</p> <p>With regard to the EESA, they write that it <i>'does not say that no information will be disclosed until Chemical similarity has been established'</i> and that they have <i>'made every effort to establish chemical similarity since March 2015, and [are] still committed to establish chemical similarity'</i>. Therefore, their request is <i>'legitimate'</i> and they <i>'do not see any issue in starting the data sharing discussion from now to facilitate the progress of [their] request'</i>.</p> <p>They ask whether they will receive the list of studies and the LoA quote by 11 September 2015 and write that they <i>'do not want to wait until a future meeting to receive this information'</i> and request a <i>'justification'</i> in case the Other Party is not able to meet the deadline.</p> <p>Finally, they ask for the Other Party's accounting details and repeat their request for the summary of the [REDACTED] endpoints.</p>	
109.	09/09/2015	Meeting arrangements	Only provided by the Other Party.
110.	09/09/2015		Only provided by the Other Party.
111.	10/09/2015	<p>The Other Party proposes to provide the [REDACTED] information by 11 September 2015 and the list of studies, LoA quote and accounting details by 18 September 2015.</p> <p>They request from the Claimant a <i>'comparable study list relating to information held by [the Claimant]'</i> as both parties <i>'could submit conflicting information to the Authorities'</i> and they would like to <i>'anticipate and manage'</i> this between the parties. Further, they write that <i>'a LoA cannot be issued [...] until the chemical similarity check has been passed'</i>.</p> <p>They also raise issues related to another substance.</p>	
112.	11/09/2015	The Claimant agrees to the proposed way forward.	
113.	11/09/2015	The Other Party send <i>'some information on the [REDACTED]'</i> .	Only provided by the Other Party; attachments provided to ECHA.

114.	15/09/2015	Meeting arrangements	Only provided by the Other Party.
115.	18/09/2015	The Other Party sends their bank details.	Only provided by the Other Party.
116.	18/09/2015	Agreement and signature of chemical similarity contract with laboratory, including confidentiality agreement with all three parties	
117.	18/09/2015	The Other Party sends a <i>'spreadsheet detailing [their] valuation of the [...] data which is subject to [the Claimant's] request for data sharing'</i> and lists the information not included. They estimate the LoA price at ██████████ EUR and underline that the LoA <i>'will become available only if chemical similarity is demonstrated'</i> .	Attachment provided to ECHA only by the Other Party.
118.	18/09/2015	The Claimant sends the list of studies owned by them.	Only provided by the Other Party.
119.	21/09/2015	The Claimant requests more information regarding ██████████ to <i>'align [their] strategy'</i> .	Only provided by the Other Party.
120.	05/10/2015	The Claimant sends the draft minutes of the meeting of 29 September 2015. The minutes address: - the progress of the dossier under the BPR - LoA price: the Claimant requested clarification and further information on (1) consultancy fees, (2) RMS fees, namely to which product types (PT) they can be attributed as the Claimant only seeks access for two out of four PTs (3) administrative costs (4) risk premium and will provide a counter offer. - specific endpoints: a larger numbers of studies were included ██████████, and parties discussed whether to review together the ██████████, potentially before purchase of the LoA. - chemical similarity: in case no chemical similarity is establish, <i>'negotiations would not be continued'</i> .	
121.	16/10/2015	The Other Party sends their comments to the draft minutes of the meeting of 29 September 2015, mainly related to: (1) the LoA price, underlining that the Other Party awaits a counter offer from the Claimant; and (2) the ██████████ endpoints, explaining the Other Party's approach to the data and	

		indicating that <i>'no agreement could be finalised'</i> regarding a common review of the data by experts from both parties.	
122.	17/10/2015	<p>The Claimant sends their counter offer and explains their approach for a number of cost factors:</p> <ul style="list-style-type: none"> <li>- RMS fees: only fees for two PTs should be considered, and a 20% reduction is applied as only access to the <i>'studies covered by the mandatory data sharing'</i> is sought;</li> <li>- limitation of use for BPR only: a reduction of 30% instead of 25% is proposed;</li> <li>- consultancy fees: they agree to ██████████ EUR for the ██████ <i>'waivers'</i> but have <i>'removed the additional costs ██████████ EUR'</i> and ask for further justification for this sum.</li> <li>- calculation rules: they agree to the risk premium of 20% and the dossier preparation costs, but propose to lower the <i>'administration/study monitoring costs'</i> to 10% <i>'as a more realistic figure'</i>.</li> <li>- inflation: they ask whether UK or EU inflation rate was applied for studies priced in GBP</li> </ul> <p>Further, the Claimant proposes to provide waivers and robust study summaries covered by the LoA. They list all the studies to which they want to purchase access, and write that they would like to <i>'access all ██████ waivers listed in your overview to ensure consistency in [the Claimant's] submissions'</i>. Finally, they ask for a <i>'brief summary of the study results'</i> for a ██████████ study and <i>'propose to swap access (balancing the study value)'</i> for endpoints where they have own data.</p> <p>Their counter proposal for the LoA amounts to ██████████ EUR.</p>	Attachments (e.g. calculations for counter proposal and list of studies) provided to ECHA
123.	21/10/2015	The Claimant agrees with the comments to the minutes and provide the final version. Further, they ask the Other Party whether they agree to jointly <i>'review the available data to avoid discrepancies between the dossiers'</i> .	Only provided by the Other Party.
124.	28/10/2015	The Claimant asks the laboratory about the progress in the chemical similarity assessment.	
125.	28/10/2015	The laboratory announces <i>'preliminary results by the end of the week'</i> .	
126.	28/10/2015	The Claimant agrees to this.	
127.	30/10/2015	The laboratory writes that following their <i>'review of the available information, the results of the chemical similarity check are inconclusive and [they] believe that if [the parties] were to submit an application to ECHA for technical</i>	

		<i>equivalence that a Tier II assessment would be required</i> '. They have asked additional input from their analytical and phys-chem teams and announce to prepare a report <i>'confirming the methodology and outcome'</i> by 13 November.	
128.	13/11/2015	The laboratory announces a delay; the report will be ready <i>'at the earliest opportunity next week'</i> .	
129.	18/11/2015	The laboratory provides the conclusions of their assessment. The reports states that the chemical similarity check is <i>'inconclusive'</i> highlighting however that <i>'as a chemical similarity check is comparable to a Tier I technical equivalence assessment, the reference source and alternative source may be determined to be technically equivalent following a Tier II assessment by ECHA however this falls outside the scope of this chemical similarity check..'</i>	Attachment (conclusions) provided to ECHA
130.	18/11/2015	The Other Party writes that the clause of the EESA would now be applicable according to which <i>'When, irrespective of the will of the Parties, no chemical similarity can be established between the specifications by the appointed consultant, the Parties will have to stop negotiating a Data Sharing Agreement'</i> .	
131.	23/11/2015	The Claimant replies that the laboratory's assessment was <i>'inconclusive, which does not mean that no chemical similarity can be established'</i> . Therefore, they argue they are <i>'in compliance with [the EESA], since [they] have made every effort to establish Chemical similarity'</i> and therefore the clause mentioned by the Other Party <i>'does not apply'</i> . They <i>'request that the data sharing discussions [...] will be continued without undue delay'</i> and request an answer to their LoA counter-offer.	
132.	Email of 01/12/2015 Letter dated 30/11/2015	The Other Party writes that the inconclusive assessment <i>'means that chemical similarity has not been established'</i> and asks the Claimant <i>'what action [the Claimant] plans to take to establish chemical similarity'</i> . They further state that they address the Claimant's questions and counter-offer once <i>'sufficient progress'</i> on establishing chemical similarity is made.	
133.	08/12/2015	The Claimant states they <i>'are still committed to make every effort to establish chemical similarity'</i> but are <i>'concerned about the additional delay with the data sharing negotiations'</i> . They write that the <i>'primary objective'</i> is to agree on data sharing, not to establish chemical similarity, and that they <i>'will be submitting an application to ECHA for conduction a Chemical similarity check before the end of this year, expecting a decision from ECHA by the end of January 2016'</i> .	

		Finally, they request a reply to their counter offer and announce to file a dispute with ECHA in case they do not get a response by 8 January 2016.	
134.	08/01/2016	The Other Party underlines that the laboratory was selected in mutual agreement and that the EESA states that the parties need to stop negotiations if <i>'the appointed consultant'</i> cannot establish chemical similarity. Therefore, the EESA <i>'essentially create[s] the prerequisite that chemical similarity should be established before data sharing negotiations can continue'</i> . Further, they underline that both parties were free to enter into this contract, making reference to data sharing disputes decisions issued by ECHA. They write that the parties are now bound by it, i.e., they need to establish chemical similarity before any further negotiations. Finally, they ask the Claimant to keep them informed about any progress with ECHA's chemical similarity assessment, stating that they <i>'would be pleased to continue data sharing negotiations'</i> if ECHA established chemical similarity.	
135.	17/05/2016	The Claimant informs that they will submit the dispute with ECHA <i>'unless immediate action is taken by [the Other Party] to address our longstanding data sharing request'</i> . They write that the Other Party <i>'unilaterally discontinued the negotiations on 8 January 2016'</i> and that they have not receive any reply to their counter offer. Further, they provide a summary of their discussions, highlighting that the laboratory <i>'has not excluded [chemical similarity] either'</i> and that due to the applicable confidentiality agreements they are <i>'unable to assess whether [REDACTED] was provided with sufficient information to make that determination'</i> . They write that the Other Party's <i>'insistence on making chemical similarity a precondition [...] is contrary to the BPR'</i> . With reference to the Practical Guide on Data Sharing published by ECHA they argue that chemical similarity <i>'cannot be a precondition to data sharing from the data owner's perspective'</i> and that it would be <i>'unlawful'</i> for the Other Party to <i>'unilaterally cease negotiating'</i> . They urge the Other Party to resume negotiations and announce to file a data sharing dispute with ECHA by 24 May 2016 if they do not receive a reply to their earlier counter offer and requests.	
136.	23/05/2016	The Other Party <i>'cannot agree'</i> with the Claimant's argumentation, and write that a dispute cannot be filed as the BPR requirement that <i>'no agreement is reached'</i> is not fulfilled.	

		<p>They reject having <i>'unilaterally discontinued'</i> the negotiations, highlighting their willingness to take up negotiations once chemical similarity is established. Further, they write that the Claimant's counter offer <i>'was well received and is being considered'</i> but pending the <i>'mutually agreed'</i> establishment of chemical similarity as laid down in the EESA discussing <i>'offers and counter-offers [...]</i> <i>seems premature now'</i>.</p> <p>They disagree with the Claimant's argumentation that insisting on the chemical similarity assessment before taking up the negotiations is against the spirit of the BPR, arguing that the Claimant <i>'freely entered into [this] commitment'</i> and rejects the argument that there was a lack of ECHA guidance on the requirement of chemical similarity at the time the EESA was signed.</p> <p>With reference to the ECHA's dispute decisions, they write that parties are required to be <i>'consistent and reliable'</i> while the Claimant's <i>'behaviour has been capricious and aimed at changing the goal posts to suit itself'</i>.</p> <p>Finally, they offer to <i>'explore with [the Claimant] how [the Other Party] can help in the establishment of chemical similarity'</i>, and state that they have <i>'in no way discontinued these negotiations'</i> and while provide their reply to the Claimant's counter offer once chemical similarity has been established.</p>	
137.	26/05/2016	Bank account statement: █████ EUR from the Claimant to the Other Party.	Only provided by the Claimant.
138.	10/08/2016	<p>The Claimant informs about their <i>'intention to submit a Data Sharing Dispute to ECHA in 1 week'</i> if the Other Party is not willing to negotiate data sharing <i>'in absence of conclusive proof of chemical similarity'</i>.</p> <p>They find the Other Party's message of 23 May 2016 <i>'extremely disappointing'</i> and write they have sought <i>'advice from independent legal counsel and have also communicated with ECHA directly, in the context of its voluntary Chemical Similarity Check Service'</i>.</p> <p>They write again that in their view the Other Party has <i>'unilaterally ceased'</i> negotiations by asserting an <i>'unachievable pre-condition'</i>. They write they have <i>'not received [...]</i> <i>any substantive response'</i> to their questions and counter-offer for dated 17 October 2015.</p> <p>Further, they address the Other Party's references to ECHA's Management Board and the Practical Guides on technical equivalence and on data sharing, writing that it is not justified to make chemical similarity a pre-condition for data</p>	The letter from ECHA to Claimant was not provided to the Other Party.

		<p>sharing negotiations and that parties cannot <i>'contract out of the BPR's binding obligations (a) to share data and (b) not to conduct testing on vertebrates which has been "repeated for the purposes of" the BPR'</i>. In addition, they state that the Other Party would have <i>'remained free (at any time during the last 10 months) to waive [their] insistence'</i> on this pre-condition.</p> <p>The Claimant further rejects being <i>'capricious'</i>. They state that they cannot know whether the chemical similarity assessment might have been inconclusive because of the information provided by the Other Party, and write that the Other Party has <i>'provided no concrete solutions'</i> to establish chemical similarity following the inconclusive assessment.</p> <p>In the following, they summarise their contacts with ECHA regarding the chemical similarity assessment, writing that ECHA concluded that could not confirm that the substances are chemically similar <i>'because the reference source in [the Other Party's] dossier is not sufficiently precise'</i>, and highlighting that ECHA's assessment is without prejudice of an assessment of <i>'technical equivalence pursuant to Article 54 of the BPR'</i>. The Claimant further quotes the letter from ECHA stating that <i>'[a]t this stage of the review of the active substance, the reference source information for [the active substance] has not yet been discussed in the working groups of the Biocidal Products Committee. These steps are necessary for setting the reference source and reference specifications of the active substance and its eventual approval under Article 9(1) of the BPR. Therefore, the outcome of the chemical similarity check is <u>only in relation to the information which is available on the reference source at the time of this assessment. [...T]he reference source information which has been used for the present chemical similarity check may be different from the information which will be available for the final approved reference source after approval of the active substance.'</u></i></p> <p>Finally, they urge the Other Party to confirm in writing that they <i>'cease relying on the chemical similarity check as a precondition for data sharing'</i> and to take up negotiations.</p>	
139.	11/08/2016	With reference to the holiday period, the Other Party requests to extend the deadline until 7 September 2016.	Only provided by the Claimant.
140.	12/08/2016	The Claimant rejects the request to extend the deadline and takes this as <i>'a further evidence that there is not real process of consideration within [the Other</i>	Only provided by the Claimant.

		<p><i>Party] of our reasonable requests by rather a delaying tactic'. However, they agree to extend the deadline to 24 August 2016.</i></p>	
141.	23/08/2016	<p>The Other Party's legal counsel writes to the Claimant, stating that <i>'the core of the ongoing [...] negotiations [...] is the [EESA]'</i>, and repeating the clauses on chemical similarity as a precondition for the negotiations. They highlight that the Claimant <i>'seem[s] to find fault with these provisions today'</i> while they <i>'explicitly accepted this condition'</i> at the time the EESA was signed. They further write that the disagreed wording was <i>'imposed by [the Claimant] in another data sharing negotiation'</i> and ask whether the Claimant <i>'can, at its sole discretion, impose/reject chemical similarity provisions irrespective of other parties' rights and expectations'</i>, challenging the Claimant's reliability in the negotiations. They make reference to the laboratory's statement that a <i>'Tier II assessment by ECHA'</i> might still find the substances technically equivalent, and write that the Claimant should have <i>'followed up on this recommendation, or discussed it'</i> with the Other Party.</p> <p>They list the information the Other Party has provided to the laboratory, writing that it is <i>'very comprehensive and likely much more detailed than that provided'</i> by the Claimant, and ask the Claimant to also disclose which information they provided to the laboratory.</p> <p>They write that they have provided a <i>'list of studies [...] and a valuation'</i>, and that information on the <i>'manufacturing process and the impurity profile [are] commercially sensitive'</i>.</p> <p>With regard to ECHA's chemical similarity assessment requested by the Claimant, the Other Party state that the Claimant <i>'believes that it can unilaterally deviate from the Agreement, which unambiguously states that that the chemical similarity assessment [...] must be done by a technical consultant agreed upon by both companies'</i>. They write that the Claimant <i>'did not invite [the Other Party] to participate in this exercise'</i>, and that they could have supplied the same information they provided to the laboratory earlier also to ECHA. Finally, they ask the Claimant to share ECHA's assessment with them. With reference to ECHA's Practical Guides, published Data Sharing Dispute decisions and the Management Board, they repeat that a chemical similarity check can be agreed under the <i>'principles of contractual freedom'</i>.</p> <p>Finally, they write that [REDACTED] cannot be repeated for the same</p>	

		<p>substance, but if the substances are not the same <i>'the only logical conclusion'</i> would be that companies may perform tests.</p> <p>They conclude that filing a data sharing is <i>'premature and ill-advised'</i>, that they have <i>'not discontinued the negotiations, not implicitly and not explicitly'</i>, and <i>'invite [the Claimant] to discuss the chemical similarity problem and possible solution during a meeting'</i>.</p>	
142.	26/08/2016	<p>The Claimant replies to the Other Party's letter of 23 August 2016, writing they find it <i>'deeply disappointing to see so many aspects [...] raised again'</i> and that negotiations seem to be <i>'going in circles'</i>.</p> <p>They announce that they will file the data sharing dispute <i>'now'</i> as the Other Party does not show <i>'substantive movement'</i> on the <i>'longstanding and fundamental request'</i> to <i>'cease relying on chemical similarity as a precondition'</i>.</p> <p>As market access requires them to be included on the Article 95 list, they <i>'simply cannot bear the prolonged negative market impacts'</i> of not having access to the Other Party's data.</p> <p>Further, they state that the <i>'common goal should be to reach an agreement, which has not been possible owing to [the Other Party's] refusal to negotiate sharing terms'</i>. They <i>'remain open'</i> for negotiations and a possible meeting <i>'even after our initiation of the dispute and would be prepared to withdraw it should an agreement be reached'</i>.</p> <p>In the following, they address the points raised in the Other Party's letter of 23 August 2016:</p> <p>They agreed that the clause in the EESA regarding a chemical similarity check was <i>'mutually agreed'</i> but underline they are <i>'in fundamental disagreement about how it may be lawfully applied'</i>: to <i>'protect the data accessor'</i> or <i>'as a bar to all negotiations'</i> enabling the data owner to avoid negotiations.</p> <p>Further, they argue that their position has not changed and has been well explained and justified in the course of the negotiations. With reference to an ECHA Board of Appeal ('BoA') decision, they further point out that a change in position <i>per se</i> is not problematic <i>'as long as it was explained'</i>.</p> <p>Regarding the possibility to perform vertebrate tests, they argue that the Other Party <i>'fundamentally misstates the rules on data sharing in the BPR and duplication of animal studies. Even where substances are not identical mandatory data sharing still applies'</i>. The Other Party <i>'cannot lawfully force [the</i></p>	

*Claimant] to duplicate [the animal studies]', underlining that 'the risk of there not being technical equivalence at the product authorisation stage [...] is upon [the Claimant]'*.

The Claimant writes they agree with the selection of the laboratory but not with 'the use of its work by [the Other Party] to bar any substantive negotiations'. They underline that 'the EESA [...] requires only Tier I' and that that 'a Tier II technical equivalence test [...] is neither envisaged in the EESA nor in the BPR' and would be 'an even higher standard'.

With a view to the information about the Other Party's substance used for the chemical similarity assessment, they conclude that 'there must be imprecision in [the Other Party's] description of the substance' and argue that the 'subject matter headings of the information [the Other Party] submitted to [laboratory]' says 'nothing about the detail and quality of the material'.

Concerning their decision to ask ECHA to perform a chemical similarity assessment, they write that this was a step to 'remove the barrier to our negotiations' and that it was in line with an ECHA BoA decision to inform the Other Party only afterwards. Regarding ECHA's chemical similarity assessment, they write that 'nothing in it justifies [the Other Party's] refusal to negotiate'. Further, they point out that the Other Party is 'inherently contradictory' in arguing on the one hand that the definition of their substance is stable while on the other hand indicating that new information has been generated. This makes establishing chemical similarity 'practically impossible to achieve'.

They also provide arguments against the Other Party's statements concerning ECHA Guidance and Management Board documents on the issue of chemical similarity as a precondition for data sharing.

Finally, they reject the Other Party's argumentation concerning the duplication of vertebrate tests, which would mean that 'private parties are entitled to entirely subvert the public policy objective of mandatory data sharing and non-duplication of animal testing'.

The Claimant announces to file the data sharing dispute.

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