

20 December 2017

*The Claimant*

[REDACTED]

*Represented by*

[REDACTED]

Sent via encrypted email and registered mail

Copy to:

*The Other Party*

[REDACTED]

Sent via encrypted email and registered mail

Decision number:

Dispute reference number:

Name of the substance:

EC number of the substance:

[REDACTED]

## DECISION ON A DATA SHARING DISPUTE

### a) Decision

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

ECHA does not grant you permission to refer to the data you requested from the Other Party.

The reasons of this decision are set out in Annex I. Advice and further observations are provided in Annex II.

### b) Procedural history

On 22 September 2017, 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 19 October 2017.

c) 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<sup>1</sup>

Director of Registration

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<sup>1</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: REASONS OF THE DECISION

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 on vertebrates. 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>2</sup> *'to all toxicological, ecotoxicological and environmental fate and behaviour studies [...] including any such studies not involving tests on vertebrates'*.

In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the documentary evidence of the negotiations as provided by the parties, to establish whether the parties made every effort to reach an agreement on sharing the studies and their related costs in fair, transparent and non-discriminatory way.

### Factual background

#### Negotiations between February 2006 and April 2015

The first contact by the Claimant to the [REDACTED] [REDACTED] ('Consortium') took place in February 2006, when the Claimant expressed the interest to join the Consortium coordinating the submission of [REDACTED] and of other [REDACTED] containing substances as active substances on the EU market.<sup>3</sup> The Consortium replied after eight months<sup>4</sup> informing the Claimant that the decision whether the Claimant could join was not taken yet, however, they would keep the Claimant informed as soon as possible on the outcome of the decision.

Between October 2006 and April 2015, there was no communication between the parties.

#### Data Sharing conference in April 2015

The Other Party organised on 22 April 2015 a [REDACTED] [REDACTED] *'Data Sharing Conference'* to which the Claimant participated. The Other Party shared the presentation of the event at the end of April<sup>5</sup> and the minutes at the beginning of June<sup>6</sup>.

Among other points, the Other Party explained in the presentation and in the minutes that it had been designated as a data submitter of the [REDACTED] Dossier' for the Consortium.<sup>7</sup> Regarding the structure of this [REDACTED] Dossier', they explained that the Consortium is supporting eight [REDACTED] substances and that the Other Party had submitted a core data set on [REDACTED] based on

<sup>2</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>3</sup> Claimant, 22 February 2006

<sup>4</sup> Other Party, 27 October 2006

<sup>5</sup> Other Party, 27 April 2015

<sup>6</sup> Other Party, 03 June 2015

<sup>7</sup> Other Party, 7 May 2015

a read-across approach. They indicated that [REDACTED] (namely the [REDACTED]) is the Rapporteur Member State for all these active substances. They also explained that there are some 'satellite dossiers' to address individual substances / product type uses, which are not shared collectively by the Consortium members, but are the responsibility of individual Consortium members.<sup>8</sup>

Regarding the base calculation for the access to the core dossier, the Other Party listed the 'historical costs of the core dossier' as containing the following items: sweat equity, [REDACTED] fees, new studies, pre-existing studies, legal fees and consultancy fees.<sup>9</sup> Further, they indicated the type and cost of the Letter of Access ('LoA') as well as the cost for the Consortium membership. Concerning the type of the LoA, the Other Party stated that '[the Consortium] is willing to give OTC (over-the-counter) Article 95 LoAs to prospective applicants. These OTC LoAs are part of the fast track approach to data sharing. [...] The OTC Article 95 LoAs grants access to the whole core [REDACTED] dossier, i.e. access goes beyond the data subject to mandatory data sharing. [...] A refund will be employed to compensate previous recipients of Article 95 LoAs.'<sup>10</sup>

The Other Party further explained that this OTC Article 95 LoA is 'subject to a total increment of [REDACTED] %'<sup>11</sup> on the cost of the core dossier, which takes into account that '[the Consortium] is willing to go beyond the scope of data subject to mandatory data sharing'<sup>12</sup> but also variables such as sub-licensing rights, risk premium, inflation and management fees<sup>13</sup>. Another option for a prospective applicant to get access to a dossier is to become a member of the Consortium. For the membership of the Consortium, the base cost is the same as in the case of the OTC LoA, but instead of the [REDACTED] % increment, there is a membership fee of [REDACTED] €. <sup>14</sup>

#### Negotiations between October 2015 and January 2017

On 21 October 2015, the Claimant expressed interest in buying the LoA, but before taking a decision, they wanted to know the number of companies sharing the LoA cost and consequently the final cost of the LoA for them.<sup>15</sup> The Other Party indicated the cost for the membership of the Consortium and for the OTC LoA and noted that the Consortium 'is continually incurring costs and the [...] figures are subject to change'.<sup>16</sup>

On 30 August 2016, the Claimant communicated that they 'are planning to submit [their] product on Article list 95'. Thus, they indicated that they need 'the LoA for the [...] core dossier' and asked the Other Party to provide them 'an actual quotation for the costs of membership and OTC Article 95 LoA'.<sup>17</sup>

On 30 January 2017, the Other Party described again the structure of the dossier and the options for accessing the dossier in line with the presentation and minutes of the April 2015 Conference. They quoted the cost for 'obtaining an OTC Article 95 letter of access to the Core [...] Dossier' to be € [REDACTED] and for the membership of the Consortium to be € [REDACTED]. They reminded that the Claimant might also need access to a satellite dossier,

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<sup>8</sup> Other Party, 27 April 2015

<sup>9</sup> Other Party, 27 April 2015

<sup>10</sup> Other Party, 27 April 2015

<sup>11</sup> Other Party, 27 April 2015

<sup>12</sup> Other Party, 03 June 2015

<sup>13</sup> Other Party, 03 June 2015

<sup>14</sup> Other Party, 27 April 2015

<sup>15</sup> Claimant, 21 October 2015

<sup>16</sup> Other Party, 22 October 2015

<sup>17</sup> Claimant, 30 August 2016



in addition to the core dossier. They further requested the Claimant to complete an every effort and secrecy agreement ('EESA') and pay a deposit before continuing the negotiations.<sup>18</sup>

Letter of Claimant dated 29 March 2017<sup>19</sup>

The Claimant returned the signed EESA. They indicated that they need access to the core dossier - and satellite dossiers if applicable and available – *'only for purposes of notification under [...] [REDACTED]'*. The Claimant also stated that they do not intend to apply for membership of the Consortium for the moment. They further requested clarifications on a number of items to better understand how the total LoA cost was formed.

First, the Claimant asked for a list of the studies in the core dossier to which Article 60 of the BPR (Data Protection Period) applies. They also asked for clarification as to how the cost items *'[I]legal fees, consultancy fees and "sweat equity"'* are attributable to *'any efforts as regard [the active substance the Claimant is interested in]'* and as to the composition of the [REDACTED] % increment. They further asked the reason for adding a *'plus fee for administration'* in addition to the deposit. The Claimant continued by requesting some clarification in respect to the information in the core dossier which is indispensable for notification of the active substance the Claimant is interested in, in particular since they understood from the April 2015 Conference that the only collective assessment for all the active substances covered by the core dossier was for the environmental assessment.

Further, they asked for clarification on the distribution of the costs, as well as on the studies included in the *'pre-existing studies'* items, which amount to more than [REDACTED] €, and on the [REDACTED] fees. On this last point, the Claimant understood that the [REDACTED] had so far worked only on one of the substances covered by the Consortium, which has [REDACTED]. Therefore, they wanted confirmation from the Other Party that any cost related to this substance is excluded from the calculation for the substance they are interested in.

The Claimant further asked whether there would be a reduction in the payable amount due to the facts that (1) the Claimant needed a data set only for one substance instead of a full category and only a LoA access, not a full access to the studies in the core dossier, and (2) the Claimant is a micro-enterprise.

Finally, the Claimant estimated that the fee for LoA access would be at the range of € [REDACTED] to € [REDACTED], based on the cost of the list of studies they considered relevant for them, as well as an estimated *'share of the general management cost'* as far as they are not attributable to another specific active substance which is not the one they are interested in. Regarding these management costs, they indicated that they are to be calculated in details once the Other Party will reply to their above questions.

Letter of Other Party dated 12 April 2017<sup>20</sup>

In their reply, the Other Party first explained that the LoA quoted to the Claimant is an OTC Article 95 LoA, which is a part of the fast track approach to data sharing foreseen in the ECHA practical guides on data sharing. The Other Party continued that the Consortium *'strongly recommends the OTC approach since it offers data sharing procedure which does not lead to additional expenses for both parties.'* They further indicated that *'If [the Claimant] does not wish to acquire an OTC LoA then the [Consortium] will reassess its historic costs. In such a case, the increments would naturally go up but [the Consortium] would also make allowance*

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<sup>18</sup> Other Party, 30 January 2017

<sup>19</sup> Claimant, 29 March 2017

<sup>20</sup> Other Party, 12 April 2017

for a decrement for LoA only access to New Data; the access to Existing Data already takes account of LoA only access.' Furthermore, the Other Party stated that 'the compensation for a LoA for Article 95 of the BPR purposes is based on the costs incurred by the [Consortium] members, plus reasonable mark-ups. These costs are entirely substantiated.' Finally, the Other Party asked the Claimant to explain the circumstances based on which the Claimant is compliant with Article 95(2) of the BPR.

The Other Party justified the data protection period until 31 December 2025 with a reference to Article 95(5) of BPR.

Concerning the increment of █%, they explained that it takes into account 'variables such as risk premium, inflation, sub-licensing rights, etc.'. Further, the Other Party indicated that several costs that, according to the general rules under Article 63 of the BPR, could be included when calculating the costs, were not taken into account (e.g. the Consortium's sweat equity for attendance at Consortium meetings only was taken into account).

Then the Other Party explained the difference between the administration fee and the deposit. They stated that the deposit aims to show the seriousness of the Claimant in applying for access to the core dossier, whereas the administration fee is applicable only for membership applications and aims to compensate internal cost to review the Claimant's application for access to data.

The Other Party continued by explaining that all active substances supported by the Consortium draw data from the core dossier, but that the data on specific active substances are in the satellite dossiers. Thus, the Claimant may need additional data from a satellite dossier of the active substance of interest for the Claimant.

Regarding the █ fees, the Other Party indicated that they are reviewing fees charged by the █, which are based on █ domestic law.

On the request of the Claimant for a discount based on its SME status, the Other Party indicated that many of the Consortium members are SMEs and thus the Other Party cannot accept the Claimant's proposal for reduction since by doing so they 'will injure interest of many of [their] own members who are SME's themselves'.

Finally, the Other Party asked the Claimant to send the list of the studies the Claimant is interested in and stated that the Claimant's calculations regarding study costs sent in their previous letter is 'farfetched'.

#### Letter of Claimant dated 19 June 2017<sup>21</sup>

The Claimant asked which information the Other Party needed regarding the Claimants' compliance with Article 95(2) BPR and requested further clarification on several points.

The Claimant asked for clarification on the nature of the 'reasonable mark ups' that the Other Party indicated to be included in the costs.

Then, coming back to the data protection period, the Claimant explained that according to their understanding of Article 95(1) BPR, it refers to data submitted for a substance/product type combination as listed in Annex II to Regulation (EC) No. 1451/2007, but not yet approved under this regulation. Since the data submitted by the Consortium refers 'to more general topics', the Claimant doubted that they are covered by Article 95(1) BPR and a data protection

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<sup>21</sup> Claimant, 19 June 2017

period until 31 December 2025.

Regarding the ■■■% increment, the Claimant asked more details ■■■ which factors were taken into account summing up to that increment.

Regarding the sweat equity, the Claimant said that they *'now understand that it only refers to attendance at meetings of the [Consortium]'* and asked for the number of these meetings and the number of participants in, order to sum up the total cost.

The Claimant further asked for an explanation on the difference between the legal fees and consultancy fees, in particular which of these fees relate directly to the Claimant's substance or to other substances covered by the Consortium.

The Claimant also provided a spreadsheet with the studies they required access to. Based on the values of all the studies listed, the Claimant calculated a total of €■■■■. Thus, they wanted to know, *'which of these studies (amounting to ■■■■ €) are actually part of the core dossier'*.

Regarding the ■■■ fees, the Claimant asked about the active substance/product type combination for which the ■■■ invoices of approximately ■■■■ € are relevant. They pointed out that if these fees were incurred for another active substance and its combinations that is not the Claimant's substance of interest, they are not willing to participate in these costs.

The Claimant also indicated that they believed that most of the Consortium members are multinational companies and asked for a list of members that are SMEs.

The Claimant thanked *'[...] for explaining the difference between the fee for administration and the deposit'*, which they understood, and pointed out that they are not intending to apply for membership and *'therefore, assume that the administration fee will not be applicable to us.'*

Finally, the Claimant asked the Other Party to explain why they think *'that "the increments would naturally go up" in case [they] would calculate costs for an LoA for [the Claimant] in more detail.'*

#### Letter of Other Party dated 14 July 2017<sup>22</sup>

The Other Party responded to the letter of the Claimant dated to 19 June 2017 with a spreadsheet on the historical costs of the Consortium ■■■■ as well as a list of studies submitted to the ■■■ as attachments.

Regarding the ■■■% increment, the Other Party referred to its experience in biocides data sharing negotiations and indicated that *'this aggregate amount of ■■■% is not high at all. For instance, a risk premium alone of ■■■% is not uncommon in biocidal data sharing negotiations. Similarly, it is not uncommon to see an increment of ■■■% in order for an Article 95 OTC LoA recipient to be able to sub-licence the data to its customer for referencing in its customer's application for biocidal product authorisation (Article 95(4) of the BPR).'* They also explained that they gave more details on the costs in the sheet ■■■■.

On the compliance with Article 95(2) BPR, the Other Party stated that they noted *'from [the Claimant's] website that [the Claimant] has been marketing a ■■■■ based biocide since ■■■■. From the information [they] have, [the Other Party] can only include that [the Claimant] has*

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<sup>22</sup> Other Party, 14 July 2017



*been and is freeriding on the efforts of the [Consortium] for a decade'.*

The Other Party explained that the protection period for the data contained in the dossiers is set out in Article 95(5) of the BPR. In this respect, they confirmed that *'the list of data in the [Consortium] has been submitted to [REDACTED] and they referred the Claimant 'to Article 60 of the BPR for further information'.*

Regarding the sweat equity, the Other Party referred to the spreadsheet [REDACTED], which contained among other information *'the numbers of meetings of the Members of the [Consortium] which have taken place'.*

Regarding the question on the difference between legal and consultancy fees, the Other Party explained that the legal fees are *'attributable to services provided by [the Other Party] to the Consortium'* and include *'legal advice and support, preparation and attendance at meetings, advocacy, task force management, negotiating with prospective applicants, etc.'* As for the consultancy fees, the Other Party explained that they *'are attributed to the support provided by [the Other Party's technical consultant]'* and include *'attendance and preparation of technical meetings, finalisation of ongoing studies, work on [Competent Authority Reports], relationships with [REDACTED], attendance of technical meetings of the [Consortium], etc.'* The Other Party further indicated that these fees are not distinguishable by active substance nor by product type supported by the Consortium and thus *'discharged by each [Consortium] Member on an equal basis'.*

Regarding the administrative fee, after reminding that it does not apply to OTC Article 95 LoAs, the Other Party further explained that *'as [the present] negotiation is not an OTC negotiation, the [Other Party] may decide to apply an administrative fee to this data sharing compensation formula with [the Claimant]'*.

The Other Party also informed the Claimant that they estimate that the Claimant *'might need another [REDACTED] % of data on top of what is in the core [...] dossier'* in order to have a complete dossier for their substance. The Other Party asked clarifications about the spreadsheet provided by the Claimant with the studies they need and whether they are interested in getting access to the studies for which they noted zero euros. They also sent back this list with a colour code in order to highlight to the Claimant, which of the studies are existing data, new data or *'non-compensated data not included in the core [...] dossier but submitted to [REDACTED]'*.

The Other Party further explained that the core dossier contains data that is specific to some active substances and other forms of [REDACTED] and is used to conclude on the different hazards. The toxicological assessment is based on each substance whereas the ecotoxicological and environmental assessment is based on [REDACTED]. In all the cases, read-across from the core dossier is used when necessary.

The Other Party explained that the fast-track approach of an OTC LoA is appropriate when the discussion does not go *'beyond what is absolutely necessary to sell and buy an LoA'*. They further emphasised that if the Claimant does not wish an OTC LoA, the Consortium *'will reassess its historic costs. In such case, the increments would naturally go up', since 'the standard approach requires more time and resources for the [Consortium] and in consequence the increments would increase.'* In this regard, the Other Party mentioned that these questions and requests require an enormous amount of time to address, thus they *'are happy to address relevant questions from [the Claimant] but the more time [they] spend on this, the more [they] invoice the [Consortium], and therefore naturally, the more [the Claimant] should pay the [Consortium] to defray these costs'.*



For the [REDACTED] invoices and fees, the Other Party explained that the [REDACTED] legislation provides a separate fee for each substance/product-type combination, but the Consortium has found an agreement with the [REDACTED] not to levy the full amount, which creates for all applicants a substantial reduction of these fees.

Regarding the question of the presence of SMEs in the Consortium, the Other Party invited the Claimant to consult publicly available information in this regard.

Finally, regarding the cost compensation by the Claimant proposed in their letter of 29 March 2017, the Other Party stated that even excluding management costs, the proposed compensation *'remains far-fetched'*.

#### Negotiations on 17 and 18 July 2017

On 17 July 2017<sup>23</sup>, the Claimant explained in which studies they are interested and why (i.e. that some studies seem to be related to another active substance only and that the Claimant has its own data on [REDACTED]). Therefore, they asked for *'a version of the full list of studies submitted with the cost associated for each study, so that [they] can recalculate [their] proposal'*. They also considered that the issues raised by them in the negotiations were only arising in the course of evaluating the cost calculation, which is a legitimate request.

On the following day, the Other Party<sup>24</sup> replied that it would be faster if the Claimant would provide an updated list of the studies they are interested in, rather than them providing the cost for nearly 2 000 studies they submitted. They indicated that even though they recognize the obligation for them to demonstrate that the cost calculation is determined in a fair, transparent and non-discriminatory manner, *'this does not amount to an obligation to address the extremely comprehensive and numerous queries from [the Claimant]'*.

#### Email of Claimant dated 21 July 2017<sup>25</sup>

In view of the negotiations *'going on for more than a year and a half'*, the Claimant came up with a new proposal, suggesting to *'allocate total cost incurred to each active substance-product type combination, so that every user pays a certain amount per combination it wishes to register for and shares the cost attributable to such combination with all those users registering for it'*. The Claimant reckoned *'this as a fair approach that in particular would take into account the extent to which access is required to the core dossier by each user'*. They considered that with this sharing model *'all enterprises would be treated in the same way'*. They further added a discount for small companies, *'as it is also applied under REACH'*.

The Claimant also explained that if this approach would be accepted by the Other Party, the Claimant *'would not insist on further examining the history of cost incurred or fairness of its distribution'*. Thus, they asked the Other Party to present their approach to the Consortium members.

#### Negotiations between 22 August 2017 and 22 September 2017

After a reminder from the Claimant on 22 August 2017<sup>26</sup>, the Other Party responded on 13 and 14 September 2017, justifying their delay in replying by the holiday period in August.<sup>27</sup>

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<sup>23</sup> Claimant, 17 July 2017

<sup>24</sup> Other Party, 18 July 2017

<sup>25</sup> Claimant, 21 July 2017

<sup>26</sup> Claimant, 22 August 2017

<sup>27</sup> Other Party, 22 August 2017, 13 September 2017 and 14 September 2017

They considered that the Claimant has not been clear on the list of the studies they would like to have access to, i.e. access to the whole core dossier or only to part of this data, and added that *'this is resulting in a list being a moving target which is confusing and not helping negotiations.'*<sup>28</sup> Therefore, they asked the Claimant to provide a list of the studies they want access to, in order for the Other Party to then *'address any outstanding points'*.

In the same email, the Other Party reminded that the Claimant has not replied to the Other Party's concerns regarding the Claimant's compliance with Article 95(2) and possible free riding. They indicated that they need this information since *'[t]his reassures both parties, which is essential for confidentiality concerns, negotiations, etc.'*

On the same day<sup>29</sup>, the Claimant replied to clarify that their new approach suggested in their message of 21 July 2017 *'was intended to cover LoA access to all the studies that would be covered by an OTC LoA'*. They explained that this approach aims *'to alleviate the burden for all the parties involved and refrain from any further discussions on separate studies or explanations for costs. This is why [the Claimant] has not provided a detailed list of studies so far.'*

On the following day,<sup>30</sup> the Claimant replied to the Other Party's comment on their compliance with Article 95(2) BPR. They explained the background of their application to be on Article 95 list and that they are in *'in constant contact with [their] national authority as well as the ECHA. Both authorities are fully aware of the particular circumstances under which [the Claimant] is active in the market'*. They further asked whether the Other Party had a possibility to present their new alternative proposal to the Consortium members, as they expected a feedback from the Consortium members.

After a reminder to the Other Party of their urgent need to be on Article 95 list<sup>31</sup>, the Claimant informed on 22 September 2017 of their intention to file a dispute, *'as (1) [the Claimant has not] received any response from [the Other Party] yet and (2) [the Claimant] heard of one of the [Consortium] members that they have not even been informed of [the Claimant's] July proposal yet and (3) the matter is becoming increasingly urgent for [the Claimant], [the Claimant] will lodge a dispute [on that date].'*

On the same day, the Claimant submitted data sharing dispute claim to ECHA.<sup>32</sup>

For its assessment, ECHA only considers the negotiations up to the moment the dispute was filed, i.e. up to 22 September 2017 (15:21 Helsinki time), and cannot take into consideration arguments or justifications that were not made during those negotiations.

## 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 challenge the points on which they disagree, give clear explanations on those and try to understand the other party's position. They further

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<sup>28</sup> Other Party, 14 September 2017

<sup>29</sup> Claimant, 14 September 2017

<sup>30</sup> Claimant, 15 September 2017

<sup>31</sup> Claimant, 21 September 2017

<sup>32</sup> Claimant, 22 September 2017

need to explore different options and make alternative proposals to unblock the negotiations in case of disagreements. Such proposals need to be clearly explained and each party needs to give the opportunity to the other to react on those. 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.

At the outset, ECHA observes that there were two phases in the negotiations.

#### First phase (up to 21 July 2017)

In the first, considerably longer phase, the Claimant and the Other Party negotiated on the possibilities and related conditions for the Claimant to access the required studies. The negotiations continued by entering into the clarifications of the details of the cost-sharing model defined by the Consortium. In this phase, both parties made some efforts to clarify the cost calculation. However, the discussion was left open in the end, because the Claimant did not come back to the Other Party on their last clarifications of 14 July 2017.

ECHA notes that, throughout the negotiations, the parties were able to agree on a very limited amount of items, such as the difference between the administration fee for becoming a Consortium's member and the deposit.<sup>33</sup> On several other items, the Other Party gave further details and justifications upon the request of the Claimant. These items were, for example, the status of the studies submitted in the core dossier and how the data in the core dossier is used for the assessment of the active substance, as well as the possible need for the Claimant to get also data from a 'satellite dossier'.<sup>34</sup> Further explanations were also given on the data protection period applied to the studies. The Other Party also communicated further information on the historical costs, on the [REDACTED] fees and related invoices and how those are linked to the historical costs, as well as on the number of meetings summing up for the sweat equity.<sup>35</sup> During the negotiations, ECHA notes that the Claimant specifically asked for clarifications on these items and that the Other Party tried to bring further explanations and justifications.

Other items of disagreement between the parties remained throughout the negotiations, without further developments on the reasoning behind their position. These items were in particular those related to (1) the [REDACTED] % increment, (2) the idea of a discount for SMEs, as well as (3) the possibility of increase of the increments in case of an assessment of the historical costs by the Other Party.

First, regarding the [REDACTED] % increment, the Claimant requested further details, in particular on the factors taken into account. The Other Party repeated throughout the negotiations that it includes '*variables such as risk premium, inflation, sub-licensing rights, etc.*'.<sup>36</sup> To justify the [REDACTED] % increment, the Other Party first referred to their experience of data-sharing negotiations, stating that the '*aggregate amount of [REDACTED] % is not high at all. For instance, a risk premium alone of [REDACTED] % is not uncommon in biocidal data sharing negotiations.*' Similarly, the Other Party also stated that an increment of [REDACTED] % for sub-licensing rights is also '*not uncommon*'.<sup>37</sup> Second, the Other Party also referred to the fact that they did not take into account in the cost-sharing model some other costs, which could have been taken into account.<sup>38</sup> However,

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<sup>33</sup> Claimant, 19 June 2017

<sup>34</sup> Other Party, 12 April 2017

<sup>35</sup> Other Party, 14 July 2017

<sup>36</sup> Other Party, 12 April 2017

<sup>37</sup> Other Party, 14 July 2017

<sup>38</sup> Other Party, 12 April 2017



apart from these general statements, the Other Party did not give more details on the way of setting of this percentage.

While the *Practical Guide on BPR special series on Data Sharing*<sup>39</sup> does not exclude the possibility to introduce some increments, including a risk premium, it also points out that the data submitter *'must justify any claim with fair, transparent and non-discriminatory reasoning; there is no scenario which per se would require the application of a risk premium.'* The Practical Guide emphasises that there should be a sound justification for such charge.

The mere reference to the percentage that the Other Party considers as common in data sharing negotiations cannot constitute a sufficient effort to justify the application of an increment in general, nor the actual factor of ■ % that they applied. Similarly, indicating that some costs were not taken into account in the model does not alleviate the Other Party from the burden to justify the various increments added to the LoA costs, as the Claimant was not able to understand whether the requested compensation is fair, transparent and non-discriminatory as required by the BPR.

Second, the idea of giving a discount in order to take into account the SME status of the Claimant was another point continuously raised during the negotiations. The Claimant indeed asked the Other Party whether there would be a reduction of the fee since they are a micro-enterprise.<sup>40</sup> The Other Party replied that many of the Consortium members are SMEs and the Claimant's proposal could not be accepted, since by doing so they *'will injure interest of many of [their] own members who are SME's themselves'*.<sup>41</sup> When the Claimant indicated their belief that most Consortium members were multinational companies and asked for a list of SME members of the Consortium,<sup>42</sup> the Other Party told them to check the size of the Consortium members themselves.<sup>43</sup> ECHA notes that none of the parties entered into a detailed discussion, nor presented a precise argumentation on whether there could be a discount for SMEs.

Third, the parties disagreed on the qualification of the negotiations as 'OTC LoA' or 'fast-track', in the sense that the Other Party considered that this point would have an impact on the costs. Indeed, facing the request for clarification by the Claimant on various items, the Other Party indicated that this would result in the LoA not being 'OTC', and in the need for them to reassess their historic costs.<sup>44</sup> They considered that this reassessment would have the consequence that *'the increments would naturally go up'*. When the Claimant asked for clarification on this statement, the Other Party indicated that the standard approach, i.e. not 'fast-track' and including replies to the Claimant's questions and requests, requires more time and resources for the Consortium. Therefore, they claimed that *'the more time [they] spent on this, the more [the Other Party invoices] the [Consortium], and therefore naturally, the more [the Claimant] should pay the [Consortium] to defray these costs.'*<sup>45</sup> The Other Party further indicated that since the negotiations were not 'OTC', the Consortium may decide to apply an administrative fee to the data-sharing compensation formula for the Claimant. When the Claimant explained that the issues they raised were aimed to evaluate the fairness of the LoA offer, which they considered a legitimate request, the Other Party replied that the data owner obligation in data-sharing negotiations under the BPR *'does not amount to an obligation*

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<sup>39</sup> ECHA's Practical Guide on Biocidal Products Regulation Special Series on Data Sharing – Data Sharing

<sup>40</sup> Claimant, 29 March 2017

<sup>41</sup> Other Party, 12 April 2017

<sup>42</sup> Claimant, 19 June 2017

<sup>43</sup> Other Party, 14 July 2017

<sup>44</sup> Other Party, 12 April 2017

<sup>45</sup> Other Party, 14 July 2017

to address the extremely comprehensive and numerous queries from [the Claimant]'.<sup>46</sup>

In practice, this means that the Other Party, when requested by the Claimant to give clarifications referred to the possibility of making the Claimant pay for these further negotiations. Such a statement is not compatible with the obligation to make every efforts in data-sharing negotiations. The prospective applicant has the right to ask for explanations on the costs that the Other Party is asking compensation for. Making every effort also means that the Other Party must answer such queries. One of the negotiating parties must not impose the costs of their negotiations on their negotiating partner. Instead, each party should bear their own cost of the negotiations. The Other Party's statement shows a lack of efforts in the negotiations and, moreover, puts pressure on the Claimant not to continue discussing the cost-sharing model.

Thus, it appears from the first phase of the negotiations that even though both parties made efforts, by clarifying their position on several items and bringing further explanations, the approach of the Other Party, in particular regarding the lack of clarifications on the █ % increment and the addition of costs on the Claimant for continuing the negotiations, showed fewer efforts. On the other hand, the Claimant did not make the effort of replying to the last substantial answers from the letter of the Other Party of 14 July 2017. However, they offered an alternative approach, which opened the second (much shorter) phase of the negotiation.

#### Second phase (from 21 July 2017)

On 21 July 2017, the Claimant made another attempt to reach an agreement by making an alternative proposal regarding the cost-sharing model, instead of going deeper into discussions on the details of the unsolved points.<sup>47</sup>

This alternative proposal was based on a division of the costs by the number of active substance and product type combinations and then by the number of companies seeking an access to the same set of data. This showed a real effort by the Claimant to unblock the negotiations and to find an objective basis for the division of costs, which implied that the Claimant (and all the other members of the Consortium) would only bear a share of the cost based on the number of active substance and product type combinations they need access to. They specifically requested the representative of the Consortium to share this proposal with its members, hoping that other members of the Consortium could also be interested in their proposal.

In a complex setting, where companies of different sizes use the same data for several active substance and product type combinations, or only for one, such a proposal may be suitable to reflect that some companies make more extensive use of the same data than others.

The Other Party did take nearly two months before replying to the Claimant's new proposal on 13 and 14 September 2017.<sup>48</sup> The Other Party justified this delay by the summer period, but also because they did not entirely understand the offer. Indeed, they indicated on 14 September that they did not understand to which studies the Claimant wanted access to, i.e. a specific list of studies or the whole core dossier, and argued that the scope of the request by the Claimant on this point is '*a moving target which is confusing [the Other Party] and is not helping negotiations*'.<sup>49</sup>

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<sup>46</sup> Other Party, 18 July 2017

<sup>47</sup> Claimant, 21 July 2017

<sup>48</sup> Other Party, 13 September 2017, Other Party, 14 September 2017

<sup>49</sup> Other Party, 14 September 2017

In view of the wholly new approach suggested by the Claimant within these complex negotiations, the Other Party may indeed have not understood the exact content and extent of the cost-sharing approach when the Claimant presented it the first time.

The Claimant subsequently clarified this, on the next day, but only waited eight days after this clarification before submitting the dispute. By doing so, they did not give the Other Party the chance to substantially react to their alternative proposal. Even though making an alternative proposal constitutes a substantial effort in the negotiations that are stuck over increments and decrements, the fact of not giving the opportunity to the Other Party to react shows a lack of effort and goes against the premise that a dispute should only be submitted as a last resort.

### Conclusion

In the first part of the negotiations, both parties made efforts to find an agreement. The negotiations were left open, however, because the Claimant made a new proposal designed to help finding an agreement, which reflected different usage of the data by the different companies. This proposal had the potential to create a new basis for the negotiations, based on objective criteria and leaving aside the contentious issues from the first part of the negotiations. However, the Claimant did not give the Other Party sufficient time to react to this new proposal before submitting the dispute. Thus, the Claimant had not submitted the dispute as a last resort, since they had not exhausted every efforts to find an agreement.

In view of the failure of the Claimant to comply with their obligation to make every effort to reach an agreement with the Other Party on the sharing of data and its costs, ECHA does not grant the Claimant the permission to refer to the studies requested from the Other Party.

ECHA stresses that, irrespective of the present decision, both parties share the common data-sharing obligation, and are therefore still required to make every effort to reach an agreement on the sharing of the data and its related costs.



## Annex II: ADVICE AND FURTHER OBSERVATIONS

ECHA urges both parties to continue their negotiations based on the present assessment and on the following general observations in order to facilitate a future agreement:

- ECHA notes that during the negotiations, the Other Party questioned the Claimant's compliance with Article 95(2) of the BPR.<sup>50</sup> In this regard, ECHA would like to emphasise that the enforcement of the legal obligations arising from the BPR is the role of the National Enforcement Authorities. Such a discussion on the parties' compliance with these obligations must not lead to delaying nor blocking the negotiations in the future.
- Making every effort to find an agreement also means that the parties explore all their means to find an agreement. In this sense, the proposal of alternative cost-sharing models based on fairness is encouraged in the negotiations, in particular if it is likely to overcome a disagreement. In order to make every effort in the future negotiations, the Other Party should reply within a reasonable deadline to such a proposal, by either accepting it or explaining possible justified concerns.
- ECHA further notes that in case the new cost-sharing model offered by the Claimant would not permit to overcome the disagreement, making every effort would mean for the Other Party to offer another approach and reply to the other concerns raised by the Claimant (in particular, in relation to the justification of the ■ % increment and to the addition of a fee for the fact of negotiating).
- The 'OTC' approach can mean that the parties may agree to estimate the costs. However, a prospective applicant cannot be forced to pay for more than he requires for his application.
- ECHA further notes that the parties in data-sharing negotiations are free to discuss and agree on various discounts, even though they are not specifically foreseen by the BPR or ECHA's Guides. However, the *Practical Guide on BPR: Special Series on Data Sharing - Introduction to the BPR and SME considerations*<sup>51</sup> explains that '*The data compensation to be paid is calculated on the basis of a fair, transparent and non-discriminatory approach and that should be no different for SMEs or for any other category of companies.*' Therefore, while SMEs can legitimately discuss within data-sharing negotiations on the possibility for them to obtain a discount, this cannot lead to blocking the negotiations. ECHA also notes that alternatives to take into account the SME status, such as payment in instalments, are mentioned in the Guide and can be considered.
- If the future data sharing negotiations would fail again, the Claimant is free to submit another dispute.

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<sup>50</sup> Other Party, 12 April 2017

<sup>51</sup> ECHA's Practical Guide on Biocidal Products Regulation Special Series on Data Sharing - Introduction to the BPR and SME considerations

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