

Prospective Applicant:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Copy to Other Party:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
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[REDACTED]

Sent via encrypted email and registered mail

| | |
|---------------------------------------|------------|
| Reference number of the dispute claim | [REDACTED] |
| Decision number | [REDACTED] |
| Name of active substance | [REDACTED] |

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

Dear [REDACTED],

On 29 February 2016, ECHA registered a claim you (the Prospective Applicant) submitted on 27 February 2016 concerning the failure to reach an agreement on data sharing with [REDACTED] (the Other Party) as well as the related documentary evidence to the European Chemicals Agency (ECHA). Data sharing had been sought for an application to be included on the Article 95 list.

To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA also requested the Other Party to provide documentary evidence regarding the negotiations. The requested documentary evidence on was submitted by the Other Party on 18 March 2016 and registered by ECHA on 21 March 2016.

Based on the documentation supplied by both parties, ECHA has decided not to grant you permission to refer to certain studies requested from the Other Party for the above-mentioned active substance.

The statement of reasons regarding the assessment of the data-sharing dispute of this decision is set out in the Annex I. General recommendations for further data sharing negotiations are provided in Annex II. The factual background regarding the data sharing negotiations can be found in Annex III.

In accordance with Articles 63(5) and 77(1) of the BPR, an appeal against this decision may be brought to the Board of Appeal of ECHA within three months of the notification of this decision. The procedure for lodging an appeal is described at <http://echa.europa.eu/web/guest/regulations/appeals>.

Yours sincerely,

Christel Musset
Director of Registration

Annexes:

Annex I: Statement of reasons regarding the assessment of the data sharing dispute

Annex II: General recommendations

Annex III: Factual background regarding the data sharing negotiations

Annex I to decision [REDACTED]**STATEMENT OF REASONS OF THE DECISION 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 Programme¹ “*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.

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 are thus expected to explore different options and make alternative proposals to unblock the negotiations in case of disagreements. Making every effort also means that when the negotiations progress, the parties are expected to continue their efforts to reach an agreement and use the dispute mechanism under the BPR only as a measure of last resort, when all other options have been exhausted.

On 30 October 2015, the Prospective Applicant submitted a dispute claim to ECHA in relation to the negotiations between the parties from 1 December 2014 to 14 October 2015. These negotiations were the subject of ECHA’s assessment included in its decision [REDACTED], which was communicated to the parties on 19 January 2016. In its assessment, ECHA found that the Prospective Applicant did not submit its dispute claim as a measure of last resort and thus did not make every effort to reach an agreement.

The Prospective Applicant submitted a new dispute claim to ECHA on 27 February 2016, which is the subject of ECHA’s assessment that is included in the present decision. That assessment covers the subsequent negotiations between the parties from 2 November 2015 to 27 February 2016, i.e., the date the new dispute claim was lodged by the Prospective Applicant.²

¹ The work programme established by the Commission under Article 16 of Directive 98/8/EC for the assessment of existing active substances which is continued under Article 89(1) of the BPR, the detailed rules of which are set out in Commission Delegated Regulation (EU) No 1062/2014.

² Note that “Annex III – Factual background regarding the data sharing negotiations” provides an overview of the entire negotiations between the parties, including those predating 2 November 2015, as the exchanges between

During those negotiations, the parties continued their discussions on the costs of the LoA to the complete active substance dossier and alternatively to a list of 35 studies³ that the Prospective Applicant had sought access to earlier. However, the parties could not come to an agreement as the gap between their respective offers remained substantial⁴.

The persisting differences between the offers of both parties were significantly impacted by the costs of the actual studies. During the earlier⁵ negotiations between the parties, the Other Party had provided the cost breakdown of the studies.⁶ The Other Party had explained that it was not able to provide evidence, in the form of actual invoices, of all the costs it had incurred per study because a number of those studies were conducted in-house and their costs were based on internal cost calculations.⁷ The Prospective Applicant challenged those costs⁸ and made a counter offer based on price quotes⁹ it had sought from an independent third party laboratory. However, despite the repeated requests of the Other Party, the Prospective Applicant did not provide evidence related to the price offers received from the independent laboratory nor did it disclose the identity of this laboratory.¹⁰

The Other Party suggested agreeing on an independent third party laboratory to “*evaluate the baseline study cost*”, i.e., the (replacement) value of the studies.¹¹ However, the Prospective Applicant did not agree to such a step, claiming that it already “*asked quotes from independent third parties*”, that “*a new quote would cover only the baseline cost for replicating the data and all other aspects [...] would remain unsolved and lead to an impasse*” and that a “*return to a study-by-study approach would regress negotiations and bring them back to the stage already abandoned in favour of a business deal*”.¹² The Other Party argued that “[b]y far the main reason for the gap between the expectations of the parties is the difference in the assumption of such replacement costs”, while highlighting that the disagreed cost factors “*do not lead to significant differences once the basis of the calculation is set by an independent expert assessment of the replacement costs*”, and that “[the parties] will quickly find a common ground on these matters if those costs are validated”.¹³

ECHA notes that the study costs are the underlying parameter for the calculation of any further cost factors and thus for the final price of the LoA. Despite the existing disagreement on the cost factors, reaching a mutual understanding on the study costs can allow the negotiations to progress and the parties to find an agreement on the requested compensation for the LoA. As the “*Practical Guide on BPR: Special Series on Data Sharing*” indicates, if studies are conducted in-house and the costs cannot be vouched because the specific invoicing documentation is missing, the parties need to reach an agreement on the replacement values. To this end, a third party could be considered to conduct the assessment of replacement costs.¹⁴

the parties from 2 November 2015 onwards are a continuation of the previous negotiations. As a consequence, ECHA’s assessment ECHA that is included in the present decision refers to the entire negotiations between the parties.

³ See references no. 44 and 46.

⁴ See references no. 72 and 76.

⁵ The parties’ negotiations between 1 December 2014 to 14 October 2015.

⁶ See reference no. 38.

⁷ See references no. 38, 41, 44, 45, 46, 51, 65, 69, 77, 78, 79, 81 and 82.

⁸ See references no. 41, 43, 44, 65, 69, 77, 78, 79, 81 and 82.

⁹ See reference no. 80.

¹⁰ See references no. 43, 45, 51, 53, 78, 80 and 82.

¹¹ See reference no. 65, 69, 71, 78, 79 and 80.

¹² See reference no. 79.

¹³ See reference no. 80.

¹⁴ See “Practical Guide: Special Series on Data Sharing – Data Sharing”, section 3.4 General rules under Article 63

Accordingly, agreeing on an independent third party to assess the replacement costs can be considered a constructive approach to progress the negotiations. Thus, by suggesting agreeing on an independent third party laboratory to evaluate the replacement value of the studies, the Other Party demonstrated that it made efforts to unblock the negotiations and find a mutually acceptable basis for the negotiations of the price of the LoA. However, by rejecting the proposal of the Other Party for contracting an independent third party to evaluate the replacement values of the studies, the Prospective Applicant effectively blocked the negotiations from progressing. Consequently, the Prospective Applicant did not comply with its obligation to make every effort to reach an agreement.

In view of the failure of the Prospective Applicant 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 Prospective Applicant the permission to refer to the studies requested by the Other Party.

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

Annex II to decision [REDACTED]**GENERAL OBSERVATIONS FOR FURTHER DATA SHARING NEGOTIATIONS**

ECHA would like to make some general observations in order to facilitate a future agreement:

- Parties to data sharing negotiations are free to agree their cost calculation model (e.g. baseline costs, regulatory management fees, risk premiums and/or profit mark-ups) but all the items included to the cost calculation model need to be transparently justifiable and fair.
- The negotiating parties are free to find an agreement on the sharing of the data and its costs, be it in the form of a "*business deal*" or based on a "*study-by-study*" approach. However, ECHA reminds the parties that the criteria of a fair, transparent and non-discriminatory sharing of data and costs need to be respected regardless of the agreed approach.
- Making every effort to find an agreement also means that the parties explore all their means to find an agreement. If a disagreement persists on a specific item, e.g., the cost of the studies, agreeing on an independent third party to assess the matter, in particular in case of missing invoices when studies have been conducted in-house, can be a constructive way forward. Refusal to ask a third party for its expert opinion requires sound justification as required by the obligation to make every effort.
- If the future data sharing negotiations would fail again, the Prospective Applicant is free to submit another claim, covering the efforts subsequent to the present decision;
- ECHA reminds both parties that the outcome of a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would. Accordingly, ECHA strongly encourages the parties to continue their efforts to reach an agreement that will be satisfactory for both parties;
- ECHA is never a party in the negotiations. Therefore, all arguments have to be communicated between both parties directly.

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 | Remark |
|----------|------------|---|---|
| 1 | 01/12/2014 | The Prospective Applicant initiates the negotiations attaching to the email a letter. | Email provided to ECHA only by the Other Party; Attachment not provided to ECHA |
| 2 | 01/12/2014 | The Prospective Applicant sends a revised version of the letter, in which the Prospective Applicant <i>"seeks to obtain regulatory access to the set of evaluated vertebrate studies [...] that are responsible for the approval of [Other Party's active substance] and placed in Article 95 under Regulation (EC) 528/2012"</i> . | Provided to ECHA only by the Other Party |
| 3 | 03/12/2014 | The Other Party confirms the receipt of the letter and informs that it is <i>"consolidating the costs for data sharing of the studies requested"</i> and will get back to the Prospective Applicant upon completion. | Provided to ECHA only by the Other Party |
| 4 | 05/12/2014 | The Prospective Applicant thanks for the Other Party's message and acknowledges receipt. | Provided to ECHA only by the Other Party |
| 5 | 09/01/2015 | The Prospective Applicant asks when it can expect the offer from the Other Party. | Provided to ECHA only by the Other Party |
| 6 | 12/01/2015 | The Other Party apologises that it is <i>"not able to provide a definite answer about the timeline"</i> on that date and promises to come back to the Prospective Applicant with a timeline for the offer after 14/01/2015. | Provided to ECHA only by the Other Party |
| 7 | 16/01/2015 | The Other Party informs the Prospective Applicant that it <i>"will provide the offer for access to the vertebrate studies and the additional studies in ecotox, tox, e-fate latest by the end of [January 2015]."</i> The Other Party indicates that prior to sharing the offer and starting negotiations it would prefer to sign a secrecy agreement and encloses a draft version of the document. | Provided to ECHA only by the Other Party |

| Ref. no. | Date | Content | Remark |
|----------|------------|--|--|
| 8 | 20/01/2015 | The Prospective Applicant agrees that <i>"it is desirable to have a secrecy agreement [...] although it is not obligatory"</i> , while suggesting some amendments to the draft agreement. | Provided to ECHA only by the Other Party |
| 9 | 27/01/2015 | The Parties agree on the details of the secrecy agreement. | Emails provided to ECHA only by the Other Party Final version of secrecy agreement provided by both Parties |
| 10 | 30/01/2015 | | |
| 11 | 02/02/2015 | | |
| 12 | 04/02/2015 | | |
| 13 | 05/02/2015 | | |
| 14 | 05/02/2015 | | |
| 15 | 06/02/2015 | | |
| 16 | 06/02/2015 | | |
| 17 | 10/02/2015 | The Prospective Applicant encloses the signed copy of the secrecy agreement and informs the Other Party that original copies will be sent <i>"by express courier shortly"</i> . | Provided to ECHA only by the Other Party |
| 18 | 12/02/2015 | The Prospective Applicant requests the Other Party to acknowledge the safe receipt of its email dated 10/02/2015. | Provided to ECHA only by the Other Party |
| 19 | 13/02/2015 | The Other Party sends the scanned copy of the signed original secrecy agreement and informs that the original document will be sent to the Prospective Applicant by courier. The Other Party encloses also the list of studies for which it <i>"would be prepared to grant access through a non-exclusive letter of access for use in the context of the regulation (EU) No 528/2012. The related compensation expected from [the Prospective Applicant] would be 5.9 Mn€."</i> In addition, the Other Party expresses its openness to discuss further during a conference call and asks the Prospective Applicant to propose a time slot for the call. | Provided to ECHA only by the Other Party |
| 20 | 13/02/2015 | The Prospective Applicant requests further information on the data sharing proposal: 1/ Study by study price; 2/ Confirmation that the listed studies <i>"represent all of the studies falling into the category of toxicology, ecotoxicology and environmental fate data required [...] for article 95 listing purposes"</i> and an explanation why certain studies have not been included in the list of offered studies; 3/ A <i>"copy of the same version of the Assessment Report and full Evaluation documents from</i> | Provided to ECHA only by the Other Party |

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| | | <i>which [the Other Party] have derived the offer".</i> | |
| 21 | 18/02/2015 | The Prospective Applicant requests acknowledgement of receipt of the email dated 13/02/2015. | Provided to ECHA only by the Other Party |
| 22 | 20/02/2015 | The Other Party acknowledges receipt of the email dated 13/02/2015 and informs being on a business trip, indicating to get back to the Prospective Applicant during the following week. | Provided to ECHA only by the Other Party |
| 23 | 20/02/2015 | The Prospective Applicant acknowledges receipt. | Provided to ECHA only by the Other Party |
| 24 | 24/02/2015 | The Other Party states that it is willing to share details about the offer and address questions listed in the email of the Prospective Applicant dated 13/02/2015, but it <i>"would prefer to do so in a [t]eleconference"</i> . The Other party offers also a face-to-face to meeting as an alternative option in case the Prospective Applicant would prefer this. | Provided to ECHA only by the Other Party |
| 25 | 24/02/2015 | The Prospective Applicant asks the Other Party to <i>"suggest dates for the teleconference to be held within the next few days"</i> and indicates being <i>"available all week"</i> . Furthermore, the Prospective Applicant requests the Other Party to advise them at that moment rather than wait for the conference call or personal meeting if the Other Party has reservations to share the information the Prospective Applicant has requested in its email dated 13/02/2015. The Prospective Applicant repeats what information it had requested, and expresses its opinion that the request is not <i>"all that unexpected or unreasonable"</i> and its wish <i>"to understand the method to reaching an offer price of [REDACTED] Euros for the studies identified"</i> . In addition, the Prospective Applicant states that it <i>"cannot assess a fair means of negotiating the price or selection of studies to purchase from [the Other Party] without this information"</i> . | Provided to ECHA only by the Other Party |
| 26 | 25/02/2015 | The Other Party informs the Prospective Applicant that <i>"further information on the method of determining the offer price and the rational for selecting the studies will be shared in the teleconference"</i> and proposes two timeslots for the teleconference. | Provided to ECHA only by the Other Party |
| 27 | 25/02/2015 | The Prospective Applicant states that <i>"[i]n the interest of progress and making the most of the conference call, [...] it would be helpful to receive advance details of the method of calculation and study by study cost breakdown."</i> The Prospective Applicant further requests the Other Party to <i>"address the [previous] request for a copy of the CAR and [e]valuation documents"</i> . | Provided to ECHA only by the Other Party |
| 28 | 25/02/2015 | The Prospective Applicant indicates its availability for the conference call on 03/03/2015 and requests the Other Party to confirm that it will send to the Prospective Applicant <i>"a more</i> | Provided to ECHA only by the Other |

| Ref. no. | Date | Content | Remark |
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| | | <i>detailed breakdown of the cost formula and study by study price offering in advance of the call</i> ". | Party |
| 29 | 26/02/2015 | The Other Party indicates the participants for the teleconference from its side and states that in its experience <i>"it will be more meaningful to share details of the offer in a personal discussion instead of exchanging e-mails as a first step"</i> , while being <i>"prepared to share further details and the assessment report after the meeting"</i> . | Provided to ECHA only by the Other Party |
| 30 | 26/02/2015 | The Prospective Applicant indicates that it will be calling from Spain and expresses its understanding for the <i>"desire [of the Other Party] to offer verbal explanation first [and] provide the method of calculation and study by study cost shortly after the conference call"</i> . | Provided to ECHA only by the Other Party |
| 31 | 26/02/2015 | The Other Party acknowledges the Prospective Applicant's acceptance of its approach. | Provided to ECHA only by the Other Party |
| 32 | 02/03/2015 | The Parties agree on the details of the teleconference. | Provided to ECHA only by the Other Party |
| 33 | 02/03/2015 | | |
| 34 | 02/03/2015 | | |
| 35 | 03/03/2015 | | |
| 36 | 03/03/2015 | | |
| 37 | 04/03/2015 | | |
| 38 | 13/03/2015 | <p>The Other Party sends the minutes of the teleconference held on 04/03/2015 enclosing the updated list of studies, the master study list with a study-by-study overview and the assessment report. The Other Party asks the Prospective Applicant to review the meeting minutes and to provide a counterproposal for the offer discussed in the teleconference.</p> <p><u>Minutes of the teleconference :</u></p> <p>The Prospective Applicant presented its <i>" interest to obtain regulatory access to tox, e-fate and ecotox studies required for a.s. approval [...] in accordance to Article 95"</i>. The Prospective Applicant requested a copy of the Assessment Report, a study-by-study cost overview of the studies included in the offer, details on the cost calculation and the rules for choosing the studies included in the offer.</p> <p>The Other Party explained that all studies included in the offer (██████ Euro) are highlighted in the study list, based on the unpublished Assessment Report. The offer includes the vertebrate</p> | Attachments (including teleconference minutes) provided to ECHA only by the Other Party |

| Ref. no. | Date | Content | Remark |
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| | | <p>studies and "additional studies in e-fate, ecotox and tox which were part of the Annex II dossier according to [the Other Party's] request". In addition, the updated study list presented in the teleconference contains seven additional studies which were not included in the original offer and which the Other Party is open to share, while adding these studies changes the offer to ██████ Euro. The Other Party further explained that "the offer covers a Letter of Access for the highlighted studies (no hard copies) for EU under BPR and sublicensing to affiliates". The Other Party presented the details used for calculation of the offer:</p> <ol style="list-style-type: none"> 1/ 50% of the total amount of <ul style="list-style-type: none"> ▪ The Actual Overall Cost of Data ▪ Regulatory Management = 30% of the Overall Cost of Data 2/ a risk compensation component representing 25% of the amount under point 1/. 3/ a mark-up add-on of 10% of the amount due to the Other Party under point 1/. <p>The Prospective Applicant "mentioned [its] expectation to get reconciliation in case additional parties will get access to the data package". According to the Other Party, the Prospective Applicant was the only company at that moment seeking access to the data.</p> <p>The Prospective Applicant asked for a differentiation between hybrid, replacement and historical costs and the Other Party explained that "the replacement costs correspond to the costs [the Other Party] would budget for studies for internal projects, regardless if these are conducted internally or contracted out".</p> <p>The Prospective Applicant pointed out that it "would not agree to the calculation of costs, especially the risk fee, management fee and market taking into account the limitation of the offer to EU". Furthermore, the Prospective Applicant mentioned that the "formula of the calculation should be given in a guidance document". The Other Party was not aware of a specific guidance on calculation of costs and pointed out that the calculation used "corresponds to industry practices". The Prospective Applicant expressed its intention to follow up on the guidance document and to come back with a counter proposal.</p> <p>The Other Party agreed to provide to the Prospective Applicant with the Assessment Report, an updated study list and a breakdown of costs study-by-study by 12/03/2015. The Other Party will not provide the CAR, while the Prospective Applicant is free to contact ECHA to get access to the document. The Parties agreed to have a follow-up meeting on 30/03/2015.</p> | |
| 39 | 20/03/2015 | The Prospective Applicant states that the minutes of the teleconference contain "few | |

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| | | <i>inaccuracies</i> " which the Prospective Applicant "would like to clarify and change for the record" next week. The Prospective Applicant requests to postpone the meeting scheduled of 30/03/2015 to enable them to better prepare the counterproposal for the data compensation offer. | |
| 40 | 24/03/2015 | The Other Party agrees to postpone the meeting, proposing to schedule a new meeting from 08/04/2015 onwards. In addition, it expresses its willingness to receive the Prospective Applicant's comments on the meeting minutes. | |
| 41 | 28/07/2015 | <p>The Prospective Applicant informs the Other Party about the change of the negotiator on its part. In the attached letter, the Prospective Applicant provides its comments and its point of view on the cost calculation formula used in the offer of the Other Party and makes its counter offer.</p> <p>The Prospective Applicant states that the baseline study costs quoted by the Other Party are "significantly higher than those [the Prospective Applicant] would pay to reputed GLP laboratories to replicate the studies". It challenges the Other Party's base line cost "as it is based on [the Other Party's] own internal assumptions and theoretical calculations which are at variance with normal industry practice". Furthermore, the Prospective Applicant states that it has obtained "quotes from [reputed GLP] laboratories and the discrepancy is very high".</p> <p>Concerning the management fee (30%), the Prospective Applicant states that "[t]he management fee applied [...] is basically a way of recovering the cost of the Annex I inclusion efforts aside from the cost of studies themselves." The Prospective Applicant challenges this approach as the "objective of data sharing is to share the cost of the studies, not to recoup other costs which are not part of the study". Moreover, the Prospective Applicant states that "the baseline cost of the study calculated by [the Other Party] is derived from its own internal standard project budgeting which already calculates its full internal overheads, risk and management premiums as part of the standard project budgeting" and "[t]herefore management fees are not appropriate since these are already taken into account".</p> <p>The Prospective Applicant states that the proposed risk fee (25%) raises three issues: 1/ No risk fee should be applied as "the data package was initially developed by [the Other Party] for other purposes and used in other jurisdictions" and therefore "the risk, if any, has been spread over a number of jurisdictions and regulatory areas and there is no additional risk left". Moreover, the Other Party "has already neutralised the risk for those studies in the</p> | |

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| | | <p><i>context of plant protection products";</i></p> <p>2/ The Other Party did not have any additional risk in "submissions under the BPD/BPR since the results of the studies were already known to [the Other Party] when submitting the dossier to EU authorities under the plant protection products system".</p> <p>3/ The method for the calculation of the risk premium is not acceptable because the risk premium is applied to the sum of the baseline cost and the management fee. "Management is not a factor that attracts a risk premium".</p> <p>Concerning the equal sharing of the costs, the Prospective Applicant states that by applying the cost calculation formula proposed by the Other Party, and taking into account that only two companies share the data, the charge is reduced to 81.25% only (and not 50%). The Prospective Applicant adds that "if additional applicants would obtain access rights these should be taken into account by way of a reconciliation mechanism".</p> <p>Concerning the 10% mark-up for profit, the Prospective Applicant states that the "mark up departs from industry norm and is not accounted for under the BBPR or similar systems. Data sharing does not trigger a profit but only a data sharing obligation whereby applicants have to share the costs involved in the data generation". The Prospective Applicant refers to the BPR and related guidelines on data sharing.</p> <p>The Prospective Applicant states that it finds the proposed cost of access to the studies "excessive" and proposes "a more balanced, fair and objective way of calculating the overall data compensation fee" which takes into account the baseline cost ("██████ Euro based on GLP laboratory quotes") increased by 5% management and risk fee, decreased by a multiplication factor of 0.5 due to use restrictions ("LoA / EU territory / BPR only") and decreased further by a multiplication factor of 0.5 to reflect the number of companies with access rights ("currently two"). This calculation results in a compensation price of ██████ Euro to be borne by the Prospective Applicant.</p> <p>The Prospective Applicant further states that this calculation results in an amount that is "significantly higher than the amount [the Prospective Applicant] would normally pay on the basis of a proportionate, volume-based share of the costs as per the model outlined in the REACH guidance" and therefore this counter offer should be perceived "as a compromise with a view to progressing matters", which "remains valid only until 18 August 2015" and "[b]eyond</p> | |

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| | | <p><i>that date [it] reserve[s] the right to seek permission to refer to the [d]ata with ECHA".</i></p> <p>Finally, the Prospective Applicant states that they <i>"look forward to receiving a draft data sharing contract with a related letter of Access for review"</i>.</p> | |
| 42 | 03/08/2015 | <p>The Other Party acknowledges receipt of the counter proposal and informs the Prospective Applicant that it needs to be discussed internally with the management and that it will react in the course of the week of 10/08/2015, while stating that <i>"the completion of the agreement by [the] envisioned deadline of August 18 is in theory still possible, but [...] is a rather ambitious target"</i>. The Other Party also informs that it will start working on a draft data sharing contract.</p> | |
| 43 | 11/08/2015 | <p>The Other Party expresses its surprise to be given the short timeline for the feedback to the Prospective Applicant's counterproposal, given the fact that the Prospective Applicant has not been in contact with the Other Party between 20/03/2015 and 28/07/2015.</p> <p>The Other Party states that it does <i>"not agree with some of the points made in [the Prospective Applicant's] letter"</i> and highlights that it has been transparent in describing the proposal and the underlying rationale. The Other Party continues that the mark-ups such as <i>"the regulatory management reflect the additional efforts to design the strategy, prepare and write the dossier, pay the necessary fees and support the evaluation process in a new regulatory environment"</i> and therefore it considers that it is <i>"fair that this significant effort from the [Other Party] which has lasted for 8 years is also compensated by [p]rospective applicants"</i>. Furthermore, the Other Party states that due to <i>"the high uncertainty about the outcome in the absence of clear guidance document for Biocidal products [...], it is considered appropriate that both studies and regulatory management investments are subject to risk premium"</i>. The Other Party recognises that applying a mark-up for profit is unusual but continues that <i>"all the above was based upon costs considerations and a company is not expected to invoice only its own costs"</i>.</p> <p>Finally, the Other Party proposes a meeting between 13 and 21 August 2015 and requests the Prospective Applicant to <i>"provide the itemized quotes for the GLP laboratories by study and other reference material to make [the Prospective Applicant's] proposal more transparent"</i>.</p> | |
| 44 | 13/08/2015 | <p>The Prospective Applicant explains the break in the negotiations by the fact that after it had received the CAR in the end of March it had done its own investigations <i>"to refine the list of studies needed and ask quotations for each study in order to have an updated and documented quotation"</i>, thus <i>"four months for such a task is not very long"</i>. The Prospective Applicant</p> | |

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| | | <p>further explains that the quote has been requested from an EU-based GLP laboratory and the obtained quote is three times lower than the quote provide by the Other Party.</p> <p>The Prospective Applicant states that <i>"the baseline cost indicated by [the Other Party] is based on its internal costs calculations which however are neither realistic nor can constitute the basis for data sharing"</i>. The Prospective Applicant further states that the Other Party <i>"do[es] not provide any further refinements of [its] offer much less a counter-proposal other than asking [the Prospective Applicant] to provide with the basis for [the Prospective Applicant's] counter-offer"</i>.</p> <p>The Prospective Applicant provides the detailed list of studies and itemised cost against the costs claimed by the Other Party. The Prospective Applicant welcomes the proposal for a meeting but indicates that a meeting would be more fruitful after it has received from the Other Party <i>"a revised quote along with a draft data sharing agreement for review"</i>. The Prospective Applicant expresses their impression that the Other Party seems to <i>"remain [...] fixed"</i> on their position and gives as an example the request for a mark-up for <i>"profit"</i> of 10%. The Prospective Applicant states that this mark-up is not an industry norm and that <i>"data sharing is an obligation under the law in order to avoid the repetition of data generation and divide up the costs rather than an opportunity for a multinational company to make further profits"</i>.</p> <p>Finally, the Prospective Applicant reminds about its right to refer the matter to ECHA.</p> | |
| 45 | 14/08/2015 | <p>The Other Party expresses its confusion with regard to the expectations of the Prospective Applicant, especially caused by <i>"the lack of communication [...] suggest[ing] that negotiations were on hold if not called off entirely"</i>, highlighting that <i>"even while [the Prospective Applicant] were checking the cost elements, [the parties] could have progressed on other items during that time"</i>. Their confusion extends to current discussions regarding the meeting with the Prospective Applicant, is it is not clear if the meeting is desired or written statements are preferred instead.</p> <p>The Other Party urges the Prospective Applicant to provide the specific list of [the Other Party's] studies which the Prospective Applicant is willing to get access to, the identity of the laboratory from which the quote for the counter-proposal was received, and <i>"the protocol/guidelines [...] used"</i>.</p> <p>The Other Party points out that the study costs included to the offer have been conducted both internally and externally. Further, the Other Party states that costs include study monitoring</p> | |

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| | | <p>costs while it is not clear if this is included in the cost calculation provided in the Prospective Applicant's counter-proposal.</p> <p>The Other Party points out that the main difference in the price offers <i>"appears in the long term toxicology and ecotoxicology"</i>, continuing that the study costs quoted in the counter-proposal of the Prospective Applicant are <i>"lower compared to published information such as the 2007 Fleischer evaluation"</i>. According to the Other Party <i>"this affects the biggest portion of the costs"</i> and <i>"having an acceptable and complete long term study package for [REDACTED] is unrealistic"</i>. Therefore, the Other Party questions the evaluation done by the laboratory for the Prospective Applicant's counter-proposal.</p> <p>Finally, the Other party encloses a proposed data access agreement.</p> | |
| 46 | 21/08/2015 | <p>The Prospective Applicant <i>"rejects [...] to place the delay upon [the Prospective Applicant]"</i>, due to the time needed to prepare <i>"a solid and documented counter-proposal"</i> and states that it is <i>"yet to receive [the Other Party's] counter-offer"</i>.</p> <p>The Prospective Applicant states that the price quoted by the Other Party, being <i>"triple than the real on the current market"</i>, when compared with the quote received by the Prospective Applicant raises many questions on how the Other Party has calculated their price. Therefore, the Prospective Applicant would like to <i>"compare like for like"</i> if the Other Party has independent invoices or quotes. The Prospective Applicant further points out that the 2007 Fleischer evaluation report is not an official or legally binding document and that it <i>"do[es] not see how Fleischer can overrule specific quotes obtained on [the active substance] for biocidal use"</i>.</p> <p>The Prospective Applicant provides a detailed overview of its offer with the related breakdown. In addition, the Prospective Applicant lists the studies to which it would like to get access. The Prospective Applicant states that if the Parties <i>"are unable to reach an agreement by mid-next week, [the Prospective Applicant] will have no choice but to refer the matter to ECHA"</i> and the Prospective Applicant requests the Other Party revert to it with a revised price offer before 24/08/2015.</p> | |
| 47 | 24/08/2015 | <p>The Other Party points out that the list of studies, for which the Prospective Applicant requires access, contains only 35 studies instead of 140 included to list of studies communicated in the teleconference of 04/03/2015. The Other party indicates that it needs to review the new list and that it will revert to the Prospective Applicant with an offer based on this new list of</p> | |

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| | | studies <i>"as soon as possible"</i> . | |
| 48 | 26/08/2015 | The Prospective Applicant encloses the feedback on data access agreement commented also in their previous communication. | |
| 49 | 26/08/2015 | The Other Party acknowledges having missed the [Prospective Applicant's] initial feedback on the draft agreement. | |
| 50 | 26/08/2015 | The Prospective Applicant informs the Other Party that they <i>"will send a request to ECHA in accordance with Article 63 of Regulation 528/2012 ("BPR") seeking permission to refer to the [Other Party's] studies and that "this email serves as a formal notification to you in accordance with the BPR guidelines". Further, they state that "since no agreement was found by the deadline, [the Prospective Applicant's] offer is no longer applicable and [they] revert for the time being to a volume-based proportionate share of the cost[...]."</i> | |
| 51 | 26/08/2015 | <p>The Other Party replies that they are <i>"clearly meeting the timeline mid of the next week"</i> as given by the Prospective Applicant in their message of 21/08/2015. It expresses its surprise to see the latest message from the Prospective Applicant and the low study costs quoted. The Other Party states that it <i>"[has] no experience with such low study costs from reputable contract labs which are evaluated acceptable by regulatory agencies in the EU or USA"</i>. The Other Party continues stating that costs based on the Fleischer evaluation <i>"shows that costs proposed by [the Other Party] were consistent with industry practices evaluated independently"</i>. The Other Party points out that certain studies are not considered in the quotation that the Prospective Applicant has provided and therefore the Other Party is <i>"not in a position accept the costs proposed by [the Prospective Applicant] as a basis for the toxicology package"</i>.</p> <p>The Other Party expresses their confusion <i>"on the significant change in the scope of [the Prospective Applicant's] request"</i> and continues that they would like <i>"to understand what is the regulatory rationale for such dramatic change in [the Prospective Applicant's] expectations"</i>. Nevertheless, the Other Party addresses the request of the Prospective Applicant and makes a revised price offer of [REDACTED] euro covering the 35 studies requested by the Prospective Applicant.</p> | |
| 52 | 28/08/2015 | The Other Party encloses an updated contract proposal (including mark-ups/comments). | Email provided to ECHA only by the Other Party Contract provided by |

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| | | | both Parties |
| 53 | 03/09/2015 | <p>The Prospective Applicant assures that the laboratories it has asked quotations are <i>"at least as reputed as the one [the Other Party is] used to use"</i>.</p> <p>The Prospective Applicant states that it finds the Other Party's offer <i>"still extremely high"</i>. The Prospective Applicant repeats all the items of the cost calculation it disagrees with including the basis for the baseline cost and related mark-ups (in particular <i>"10% for profit"</i> since the Other Party <i>"is not here to make extra money"</i>) as well as the administration/management, risk and <i>"other intangible costs"</i>. In addition, the Prospective Applicant claims that that the Other Party has already partly absorbed the cost with the inclusion of [active substance] in Annex I to Council Directive 91/414/EEC through Commission Directive 2004/58/EC.</p> <p>The Prospective Applicant expresses its view that its <i>"approach and related offer is fair and well balanced"</i> and that it expects to receive <i>"an equally fair and well balanced offer from [the Other Party]"</i>. However, based on its experience the Prospective Applicant proposes <i>"to move the discussions towards a more straight forward business deal"</i>.</p> | |
| 54 | 07/09/2015 | <p>The Other Party comments that both parties <i>"believe that their own offer meets the criteria of being fair, transparent and non-discriminatory"</i> but there are certain cost items (<i>"study costs, regulatory management and risk components as well as reasonable profit"</i>) on which the parties have not been able to agree.</p> <p>The Other Party expresses their willingness <i>"to explore a compromise which can be the basis of a mutual agreement"</i>, however asks the Prospective Applicant to clarify what is meant with <i>"a more straight forward business deal"</i>.</p> <p>Finally, the Other Party expresses its belief that <i>"a meeting would facilitate more interactive exchanges and [...] design a possible agreement"</i> and proposes a meeting in mid-September in Mannheim or Frankfurt.</p> | |
| 55 | 18/09/2015 | The Prospective Applicant welcomes the acceptance of the Other Party to <i>"proceed on the basis of an overall business proposal rather than a study-by-study technical discussion"</i> and proposes a meeting mid-October in Brussels. | |
| 56 | 18/09/2015 | Arrangements for the meeting of 22/10/2015 in Brussels | |
| 57 | 18/09/2015 | | |
| 58 | 22/09/2015 | | |
| 59 | 24/09/2015 | | |

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| 60 | 24/09/2015 | | | | | | | | | | | |
| 61 | 12/10/2015 | | | | | | | | | | | |
| 62 | 13/10/2015 | | | | | | | | | | | |
| 63 | 14/10/2015 | | | | | | | | | | | |
| 64 | 02/11/2015 | The Prospective Applicant encloses the draft minutes of the meeting of 22/10/2015 in Brussels for the Other Party's approval and/or comments by COB 9 November. The Prospective Applicant asks if the Other Party is " <i>prepared to make a revised offer to [the Prospective Applicant]</i> ". In case it is not, the Prospective Applicant would " <i>insist on receiving a more detailed itemised breakdown for each study and related costs and mark ups</i> ". | | | | | | | | | | |
| 65 | 02/11/2015 | <p><u>Draft minutes prepared by the Prospective Applicant</u></p> <p>1. Background The Prospective Applicant described the background for its data sharing request. The Prospective Applicant also explained that it had made a request to ECHA before 01/09/2015 for inclusion on the Article 95 list. Furthermore, the Prospective Applicant stated that "<i>[n]o data sharing complaint has been submitted by [the Prospective Applicant] to ECHA for this active substance-PT combination</i>".</p> <p>2. List of Studies The Prospective Applicant explained the reasons for reductions of the number of the studies for which access is sought. Nevertheless, the Prospective Applicant stated that "<i>if a business deal can be reached for the entire package of data and this is reasonable, [the Prospective Applicant] will also consider this</i>".</p> <p>3. Offer and Counter-Offer The present offers and counter-offers were outlined to be:</p> <table><tr><th>Scope</th><th>Other Party / k€</th><th>Prospective Applicant / k€</th></tr><tr><td>Full dossier</td><td></td><td></td></tr><tr><td>35 studies</td><td></td><td></td></tr></table> <p>The Other Party explained its cost calculation for the list of 35 studies which included:</p> <p>a. Baseline study cost</p> <p>b. Regulatory management fee ("<i>fees paid to authority, expert meetings, scientific time</i>") of 30 % applied to point a.</p> <p>c. Adapted risk component ("<i>takes into account studies [that] were used in different</i></p> | Scope | Other Party / k€ | Prospective Applicant / k€ | Full dossier | | | 35 studies | | | |
| Scope | Other Party / k€ | Prospective Applicant / k€ | | | | | | | | | | |
| Full dossier | | | | | | | | | | | | |
| 35 studies | | | | | | | | | | | | |

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| | | <p><i>regulatory framework but bearing in mind [that] different authority can evaluate studies on a different basis") of 20 % (previously 25 %) applied to a. × b.</i></p> <p>d. The share to be paid by the Prospective Applicant being 40 % of a. × b. × c.</p> <p>e. Profit of 10% added to d. and calculated by a. × b. × 0.4 × 0.1.</p> <p>The Other Party noted that the offered price is significantly lower than what it would have been if the originally proposed cost calculation formula had been used. The Other Party indicated this to be "a significant step from [the Other Party] to reflect some of the [Prospective Applicant's] points". Finally, the Other Party indicated that if a third party will get a LoA in the future, the cost will be "divided into shares of 29 % for two applicants and 32 % for [the Other Party]".</p> <p>The Prospective Applicant stated that the cost calculation "formula is clear but study costs and related mark ups are not transparent enough as there is no explanation as to what concrete items constitutes those amounts (i.e. in terms of management, risk etc.)". The Prospective Applicant added that the studies had already been used for the plant protection product dossier so there is no "new risk" or "management cost involved" since "the studies were already known and available".</p> <p>The Other Party pointed out that the study list and study costs were explained in March 2015 and that the price is "based on the price [the Other Party] would ask for these studies now and also what would be asked of [the Other Party] if [the Other Party] asked third party laboratories to produce these studies". The Prospective Applicant stated that "the study costs appear to be therefore replacement costs and are not based upon [the Other Party's] invoices". The Other Party replied that for "tox studies, the replacement costs would be valid" and the costs are really those which "[the Other Party] has incurred internally". The Prospective Applicant asked for "proof of these costs by way of original invoices, itemised costs for management and study development". Finally, the Other Party proposed that "both parties could ask a lab to evaluate the baseline study costs".</p> <p>Then the Prospective Applicant outlined its cost calculation model:</p> <p>a. Baseline study cost (based on cost if the studies were repeated).</p> <p>b. Regulatory management fee of 5 % applied to point a. ("[T]he data has already been used and submitted in separate regulatory process").</p> <p>c. No risk component ("[The Prospective Applicant] discounts that any risk was existent given</p> | |

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| | | <p><i>that the studies were already used for pesticides")</i>.</p> <p>d. Restriction to the Regulation 528/2012, LoA and EEA only resulting to 50 % decrement applied to a. × b.</p> <p>e. Division for cost sharing resulting to 50 % decrement applied to a. × b. × c.</p> <p>f. In case a third party would get access to the data in the future, a refund mechanism should be applied.</p> <p>The Parties concluded that <i>"their respective positions were clear and significant differences remained on every single input for the cost compensation formula"</i> and therefore <i>"it would be difficult to come to financial agreement"</i>.</p> <p>4. Further discussion on the individual cost items</p> <p>4.1 Profit increment</p> <p>The Prospective Applicant pointed out that <i>"[the Prospective Applicant] should be sharing only a portion of the actual costs incurred by [the Other Party] and not grant [the Other Party] an extra profit"</i> and that <i>"the data sharing is not about profit but cost sharing as [the Prospective Applicant] cannot replicate some of the studies by law"</i>. The Other Party argued that <i>"[the Other Party] is not a non-profit organisation"</i> but <i>"the profit can be ignored as it is not integral"</i>.</p> <p>4.2 Management cost increment</p> <p>The Other Party stated that the management costs have to be added to the study costs due to the lot of meetings with ECHA etc. on getting the dossier through. The Prospective Applicant asked how the Other Party had come to the specific, increment amount, which seemed very high to the Prospective Applicant. The Other Party explained that when <i>"[the Other Party] started there was no guidance on exposure assessment"</i> and <i>"[o]nce the guidance came out, [the Other Party] had to rework the entire assessment"</i>. The Prospective Applicant requested the Other Party to <i>"quantify its time and people hours"</i>. The Prospective Applicant repeated its proposal of 5 % for the management fee given that the studies and their outcome were already known to the Other Party when the Other Party made its application for biocidal use. The Other Party argued that the 5 % <i>"cannot include the time put into the project management"</i> whereas the Prospective Applicant counter-argued that <i>"the increment is applicable only for the costs of the studies and cost for submitting the dossier"</i>. The Other Party replied that the <i>"30% increment does not take into account the management for the risk assessment etc, and is only applicable to those studies which [the Prospective Applicant] has</i></p> | |

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| | | <p><i>asked for</i>". The Prospective Applicant summarised its position by stating that "<i>management fee should be for new study generation only and not for regulatory costs on existing studies</i>". The Prospective Applicant added that ECHA refers in guidance documents to "<i>'generation' of data, not to regulatory monitoring</i>".</p> <p>4.3 Risk increment The Prospective Applicant stated that as the "<i>studies have already been used in pesticides and their outcome was known, no risk may be claimed</i>". The Other Party disagreed with this by pointing out that "<i>use of these same studies in different regimes is not the same</i>". The Prospective Applicant stated that "<i>this is taken into account in the 5% increment proposed by [the Prospective Applicant]</i>".</p> <p>4.4 Decrements for equal sharing and restrictions to LoA, BPR, EEA, etc The Prospective Applicant noted that as the equal sharing (50-50) applies, the 60 % decrement proposed by the Other Party appears to have given to restriction to the BPR, LoA, EEA etc. only a 10 % share, which it finds "<i>extreme low and not justified</i>".</p> <p>4.5 Business deal The Other Party expressed their opinion that "<i>the parties need to come to an agreement but perhaps should not continue negotiating on small percentage amounts</i>" and pointed out that at the moment the Parties' offers were far apart. The Other Party indicated that their business colleagues would need two to three weeks to formulate business deal offer. The Prospective Applicant indicated that the lines taken in the provided draft data sharing agreement could be followed although the Prospective Applicant indicated that they will "<i>look to an instalment plan and include a refund mechanism</i>". However, the Prospective Applicant further indicated that refund mechanism may be ignored and the agreement may be restricted to Article 95(4) of the BPR and to only one product type, if this decreases the price.</p> <p>The Parties agreed that the Other Party will make a business deal offer to the Prospective Applicant by 12/11/2015.</p> | |
| 66 | 09/11/2015 | The Other Party indicates to send the Other Party's comments to the minutes on 10/11/2015. | |
| 67 | 09/11/2015 | The Prospective Applicant thanks the Other Party for the information. | Provided to ECHA only by the Other Party |

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| 68 | 10/11/2015 | <p>The Other Party provides the minutes of the meeting with its mark-ups. The Other Party asks the Prospective Applicant to indicate if it has any further comments or questions; or otherwise, to indicate its agreement.</p> <p>The Other Party indicates that it <i>"will come back to [the Prospective Applicant] shortly on the other action points as discussed during [their] meeting"</i>.</p> | |
| 69 | 10/11/2015 | <p><u>Draft minutes with the Other Party's markups</u></p> <p>3. Offer and Counter-Offer</p> <p>The Other Party corrects that its offer for the access to the full dossier was [REDACTED] instead of [REDACTED]. The Other Party adds that the Regulatory management fee, included in its offer, was composed also of <i>"submission strategy"</i> and <i>"BPR dossier writing"</i> in addition to <i>"fees paid to authority, expert meetings, scientific time"</i>. The Other Party also further clarifies that the 40 % share required in their cost sharing model from the Prospective Applicant (being less than 50 %) reflects <i>"the type of access right which would be granted"</i>.</p> <p>The Other Party also corrects that the share of costs of the Other Party, in case a third party would get the access to the data, would be 42 % instead of 32 % which maintains <i>"a relative share of cost for [the Other Party] 50 % higher than for parties with a right to reference for BPR in EU"</i>.</p> <p>The Other Party adds that significant differences remained not only <i>"on every single input for the cost compensation formula"</i> but also for <i>"the study costs"</i>. Finally, the Other Party reformulates the parties' difficulty to come to a financial agreement to the form that they have difficulty to come to <i>"an agreement that requires consensus on a particular calculation formula"</i> and hence discussion on a business deal will follow.</p> <p>4. Further discussion on the individual cost items</p> <p>4.1 Profit increment: The Other Party clarifies the justification for the profit increment by adding that <i>"the share of study costs and regulatory management to which the profit applies is solely based on costs"</i>. The Other Party further adds that <i>"as it is not [the Other Party's] business to make profit out of data access, the % applied was barely above typical values considered for intra company sales and therefore can be considered reasonable"</i>. Furthermore, the Other Party reformulates the statement that profit increment could be ignored to the form that <i>"profit component should not be the blocking point as it is the smallest part of the compensation"</i>.</p> <p>4.2 Management cost increment</p> | |

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| | | <p>The Other Party changes the statement "5 % cannot include the time put into the project management" to the statement "5 % cannot include the time put into regulatory management for such process which takes years and requires dossier preparation and defense". The Other Party removes the statement that the 30 % increment "does not take into account the management for the risk assessments etc." and keeps only the statement that the increment is "only applicable to those studies which [the Prospective Applicant] has asked for". The Other Party adds that "only a share is allocated to [the Prospective Applicant]" and points out "with no dossier submission, there [is] no listing of active substance and therefore, such efforts and costs should also be part of the compensation".</p> <p>4.3 Risk increment The Other Party adds that "[t]he points raised by [the Prospective Applicant] on the risk were already reflected by [the Other Party] when the risk component was lowered from 25% to 20 %".</p> <p>4.4 Decrements for equal sharing and restrictions to LoA, BPR, EEA, etc The Other Party adds that "with the 60% share for [the Other Party] versus the 40% for [the Prospective Applicant], [the Other Party's] share of costs is -50% more than [the Prospective Applicant's] one" and "[t]his is why [the Other Party] believes that its proposal reflects the type of access and rights granted to [the Prospective Applicant]".</p> <p>4.5 Business deal The Other Party adds that "[a]s the biggest difference is on study costs, a proposal was made by [the Other Party] to select a contract lab which would quote studies and this number would be used by both parties". Furthermore, the Other Party adds that the Prospective Applicant "had indicated the option to develop a business deal to come to a possible agreement more quickly" as "an alternative to a deterministic approach".</p> | |
| 70 | 16/11/2015 | The Prospective Applicant thanks for the comments on the draft minutes of the meeting and asks for indication when the Prospective Applicant can expect the revised offer from the Other Party. | |
| 71 | 17/11/2015 | The Other Party states that a business deal offer could be based on the Prospective Applicant's readiness "to waive any right to receive a share of any future compensation payment by any third party to [the Other Party] for access to the data under discussion", but that the scope of the data access and the rights the Prospective Applicant seeks and the compensation which the | |

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| | | Prospective Applicant is prepared to commit are not clear sufficiently clear. Therefore, it asks the Prospective Applicant to make a <i>"more explicit proposal"</i> by 30/11/2015. Finally, the Other Party states that they <i>"uphold [their] offer and agreement to overcome the main difference in valuation by selecting a third party who shall determine the costs for a hypothetical repetition of the studies of interest in a way that is binding for both parties"</i> . | |
| 72 | 12/12/2015 | The Prospective Applicant expresses their surprise that <i>"[the Other Party] did not make an offer for a 'business deal' covering the whole [active substance] data package as agreed during [their] meeting"</i> . The Prospective Applicant points out that <i>"[i]t was indeed for [the Other Party] to make such an offer [...] because it is access to [the Other Party's] data that is at stake"</i> . Furthermore, the Prospective Applicant states that they hope that the <i>"delay in sending an offer is not indicative of other reasons that [the Other Party] may have for not progressing matters"</i> . In any case, the Prospective Applicant increases its offer by 20 %, i.e., to █████ €, for access to the full file needed for Article 95 BPR purposes. Finally, the Prospective Applicant indicates that the offer expires by 10/01/2016. | |
| 73 | 16/12/2015 | The Other Party asks the Prospective Applicant to clarify the scope of its request and the studies it is seeking access to by 18/12/2015. The Other Party also asks the Prospective Applicant to indicate when it plans to send the finalised minutes of the meeting of 22/10/2015. | |
| 74 | 16/12/2015 | The Prospective Applicant indicates that the Prospective Applicant is prepared to <i>"limit its sub-licensing rights under 95(4) BPR and have all registrations in the name of [the Prospective Applicant]"</i> as well as <i>"waive a share of reimbursement of the fees paid third parties"</i> . Regarding the scope of the access rights, the Prospective Applicant states that <i>"these are EU-wide for all product types covered by the dossier submission in relation to any existing/new products"</i> . The Prospective Applicant further indicates that as they are negotiating a <i>"business deal"</i> , the Prospective Applicant's request must be understood <i>"as covering the whole package needed to be placed on the list of authorised suppliers under Article 95(1) BPR"</i> . Finally, the Prospective Applicant indicates that it is looking forward receiving the Other Party's offer by 18/12/2015 COB. | |
| 75 | 18/12/2015 | The Other Party states that the Prospective Applicant's responses clarify the expectations of the Prospective Applicant. The Other Party acknowledges the concessions suggested by the Prospective Applicant but also recognises that difference in the offers by each party pose <i>"a significant challenge on which both companies need to work to develop a possible agreement"</i> . The Other Party indicates that it is targeting to get back to the Prospective Applicant with a proposal by 10/01/2016. | |
| 76 | 11/01/2016 | The Other Party offers to the Prospective Applicant the right to refer through a letter of access | |

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| | | at the price of [REDACTED] euro for the whole study package, i.e. a “reduction of 55 %” compared to its initial offer. The Other Party also proposes that if the Prospective Applicant has a specific financial threshold that it is not considering to exceed at the first step, it would be possible to limit the rights to specific countries or specific applications and thus reduce the amount of the first payment. If this would be integrated to the agreement, the Other Party could “ <i>extend the scope of the rights at a later stage against additional compensation</i> ”. Finally, the Other Party asks feedback from the Prospective Applicant “ <i>within the next 10 working days</i> ”. | |
| 77 | 18/01/2016 | <p>The Prospective Applicant points out that the negotiations between the Parties have started more than a year ago but they have not been able to reach an agreement. The Prospective Applicant recaps the main events in the negotiations including the provision of the list of relevant studies and the overall price offer by the Other Party in the March 2015, the search of independent quotes from third party laboratories by the Prospective Applicant, the discussions between the Parties over the summer and in the autumn and a critical meeting on 22/10/2015. In reference to the meeting on 22/10/2015, the Prospective Applicant summarises its view on the issues of disagreement, namely the lack of a breakdown and supporting evidence/documents of the costs of the studies offered by the Other Party and the cost calculation method proposed by the Other Party which included 10 % increment for profit, 20 % risk premium and 30 % management fee. On the contrary, the Prospective Applicant offered to pay a 5 % markup as a compromise. The Prospective Applicant further states that “<i>the meeting ended with a significant gap between [the Other Party’s] offer [...] and [the Prospective Applicant’s] counter-offer</i>”.</p> <p>The Prospective Applicants states that “<i>as a further and last attempt to bridge the gap between the two companies, it was agreed to consider a ‘business deal’</i>”. The Prospective Applicant further states that it increased its offer and “<i>made a number of significant concession</i>” but “<i>after further exchanges and on the basis of [the Other Party’s] last offer, the financial gap between the two offers remains significant</i>”. The Prospective Applicant concludes that “<i>[t]he negotiations have reached an impasse</i>” and the Prospective Applicant “<i>has no other choice than formally requesting ECHA to grant permission refer to [Other Party’s] data package pursuant Article 63 BPR</i>”. Finally, the Prospective Applicant indicates that it will launch the dispute before the end of the week.</p> | |
| 78 | 22/01/2016 | The Other Party “ <i>respectfully reject[s] the view that the negotiations have reached an impasse</i> ” because in their view “ <i>the last exchanges [...] between the October 2015 meeting and January 2016 showed significant progress [...] and [the Other Party] has made significant</i> | |

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| | | <p><i>adaptations to its compensation model and expectations for this purpose". Furthermore, the Other Party states that it also proposed "a path forward to close the remaining financial gap", but the Prospective Applicant "did not provide any comment to such alternative paths forward".</i></p> <p>Regarding the justification of the study costs and markups, the Other Party states that it has provided the itemised costs and the basis for most of the study costs is "<i>replacement cost or a lower figure</i>". Further, the Other Party states that the published information from Fleischer (2007) demonstrates that the individual study costs used by the Other Party were reasonable but the Prospective Applicant rejected the use of this reference.</p> <p>The Other Party repeats its proposal "<i>to engage a third party to conduct the assessment of the replacement costs</i>". The Other Party also indicates that it is "<i>expressly prepared to submit the matter to an arbitration body and commit to accept the arbitration order within the financial frame already discussed between the Parties</i>".</p> <p>Regarding the regulatory management costs the Other Party states that the basis for the regulatory management costs have been explained to the Prospective Applicant in several occasions and a 5 % markup is "<i>not a fair evaluation of the cost in this context</i>". However, the Other Party indicates that in their latest offer the regulatory management markup ends up close to 5 %.</p> <p>The Other Party expresses its surprise that "<i>the question of delay is raised by [the Prospective Applicant]</i>". The Other Party further states that it has "<i>demonstrated a constant and consistent good faith effort [...] to move towards an agreement in a timely matter</i>" whereas "<i>a lot of time has been lost waiting for [Prospective Applicant's] feedback</i>".</p> <p>The Other Party expresses its disappointment that it learned from ECHA that the Prospective Applicant had filed a data sharing dispute claim shortly after their meeting on 22/10/2015 without an indication to the Other Party. Nevertheless, the Other Party expresses its willingness to continue the negotiations with the Prospective Applicant.</p> | |
| 79 | 06/02/2016 | <p>The Prospective Applicant states that based on the email of the Other Party dated 22/01/2016 the situation remains unchanged for the following reasons:</p> <ol style="list-style-type: none"> 1. The email "<i>does not introduce any new elements compared to those set out in [Other Party's] previous offer</i>". | |

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| | | <ol style="list-style-type: none"> 2. The gap between the respective offers of the Parties is 450 %. 3. The fact that the Other Party decreased its offer by almost 60% indicates that the <i>"previous offer was exorbitant"</i>. 4. The Prospective Applicant does not see <i>"what else can be done to reduce the gap between the two financial offers"</i> since the Prospective Applicant has <i>"increased its offer by 20 % and restricted its rights to a maximum"</i>. 5. The Prospective Applicant's offer is <i>"very reasonable"</i> taking into account that the Other Party has used the studie across continent, under several regulations, and for several active ingredients. 6. As the Other Party does not provide new documentary evidence to support its figures or introduce new element that would create a new dynamic in the negotiation, the Other Party seems to be <i>"happy with continuing discussing [...] offers indefinitely, since [the Prospective Applicant] is in the meantime out of market"</i>. 7. The Prospective Applicant had already in August informed the Other Party about its intention to request the permission to refer from ECHA. The Prospective Applicant did such a request in the end August to ECHA but in the format which was not accepted by ECHA whereas the resubmission in the end of October was accepted. That does not mean that negotiations would be over in August and indeed they had continued negotiating for several months when the resubmission was done. 8. The Fleischer list is relevant standard for pricing studies only under REACH and in <i>"cannot overrule actual quotes from laboratories such as those obtained by [the Prospective Applicant]"</i>. 9. The Other Party's proposal to seek a third party assessment of the study costs is not helpful because <ol style="list-style-type: none"> a. Prospective Applicant has already asked quotes from independent third parties in support of its figures b. a new quote would cover only the baseline cost for replicating the data and all the other aspects such as administrative fees, risk premium, profit margin as well as use restrictions and related mark down factors would remain unsolved and lead to an impasse. c. Return to a study-by-study approach would regress negotiations and bring them back to the stage already abandoned in favour of a business deal. 10. The Other Party's proposal is unfair and disproportionate and the adverse effects for the Prospective Applicant <i>"goes at the core of its activity and sustainability as a SME willing to</i> | |

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| | | <p>enter the biocidal market in the EU".</p> <p>11. Finally, the Prospective Applicant repeats its intension to seek permission to refer to the Other Party's studies from ECHA.</p> | |
| 80 | 12/02/2016 | <p>The Other Party regrets that the Prospective Applicant "<i>does not acknowledge any new initiative from [the Other Party] to resolve the difference</i>", namely the proposal to "<i>to engage a third party to conduct the assessment of the replacement costs and to have an arbitration body decide on the adequate compensation</i>" but instead the Prospective Applicant has decided to refer the matter to ECHA.</p> <p>The Other Party outlines that "[b]y far the main reason for the gap between the expectations of the parties is the difference in the assumption of such replacement costs" and continues by stating that the assessment of the replacement costs could "<i>unblock the negotiation process considerably</i>". The Other Party further states that "[the Prospective Applicant's] reference to allegedly obtained quotes from allegedly independent third parties is not helpful as these suggest study costs which are far below [the Other Party's] experience, which is why [the Other Party] proposed to have the replacement cost verified by an independent expert".</p> <p>With a view to the disagreement on the application of the cost factors, the Other Party highlights that "<i>these do not lead to significant differences once the basis of the calculation is set by an independent expert assessment of the replacement costs</i>" and underlines that it is "<i>convinced that [the parties] will quickly find a common ground on these matters if those costs are validated</i>".</p> <p>The Other Party refutes the Prospective Applicant's "<i>imprudent interpretation</i>" that "<i>the first offer has significantly decreased because it was exorbitant in the first place</i>". The Other Party clarifies that as the Prospective Applicant had accepted restrictions for the right to refer to the Other Party's data, it was "<i>fair and equitable</i>" to reflect this in the compensation expected from the Prospective Applicant. The Other Party further indicates that other points made during the negotiations as well as the use of the studies for other purposes and for other geographical areas by the Other Party were taken into account when the requested compensation was calculated.</p> <p>The Other Party also refutes the accusation of taking delaying tactics. The Other Party refers to</p> | |

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| | | <p>the response times of the Parties to each other's requests and concludes that "<i>factual evidence denies any allegation against [the Other Party] regarding possible delaying tactic</i>".</p> <p>The Other Party appreciates the Prospective Applicant's clarification on filing the dispute in the end of August and resubmitting it in October. However, the Other Party states that they fail to understand why the Prospective Applicant documented to the minutes of the meeting of 22/10/2015 that they have not filed a dispute to ECHA if they had done so in August.</p> <p>Regarding the SME status of the Prospective Applicant and the statement that they are not yet on the market, the Other Party stated that the BPR regulation "<i>does not foresee different data requirements depending on the business size</i>". The Other Party continues that the Prospective Applicant's "<i>limited resources</i>" were addressed in the Other Party's proposal on 11/01/2016 for the step-wise approach for specific countries or applications but the Prospective Applicant has not reacted on that. The Other Party further states that while it is "<i>willing to trust [the Prospective Applicant's] word, [the Other Party is] wondering why several websites in the EU [...] are offering for sale still today a [Prospective Applicant's] product [...] containing [the active substance]</i>".</p> <p>The Other Party states that the Prospective Applicant seems to oppose a study-by-study approach in the context of a business deal whereas the view of the Other Party is that "<i>a Data Owner must still develop an approach which is fair and equitable for any Prospective Applicant who wishes to have access to the data</i>". In this context, the Other Party fails to understand why Prospective Applicant complains about the level of justifications of the study costs which the Other Party have provided "<i>at the very first stage of the process</i>" while the Prospective Applicant has neither provided detailed quotes or any indications which laboratory it has used to establish the baseline costs, nor accepted the Other Party's proposal "<i>to use a third party mutually agreed to come up with an evaluation which would not be disputed</i>".</p> <p>Finally, the Other Party states that it is "<i>ready to make suggestions for independent experts if [the Prospective Applicant] agree to this approach</i>". The Other Party also "<i>suggest to initiate arbitration in parallel in order to save time</i>".</p> | |
| 81 | 19/02/2016 | <p>The Prospective Applicant states that the figure asked by the Other Party as a compensation of the data is "<i>disproportionate having regard to the very limited rights that are offered to [the Prospective Applicant]</i>". The Prospective Applicant further states that as the Other Party "<i>is</i></p> | |

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| | | <p><i>now proposing to defer the price determination to a third party arbitrator”, the Other Party “essentially concedes that the parties have exhausted all their efforts to reach an agreement via bilateral negotiations”. Based on this, the Prospective Applicant informs that it “will inform ECHA that [...] the parties have reached an impasse in their negotiations”.</i></p> <p><i>The Prospective Applicant points out that “[a]ccording to Article 63(1) BPR, when negotiations between the parties reach an impasse, an ‘every effort’ agreement may only be replaced – and not complemented – by arbitration or litigation [...]. [The Other Party] is entitled to claim a fair share of the cost of studies before the competent jurisdiction or arbitration panel [...] but that cannot prevent ECHA from taking a decision allowing [the Prospective Applicant] to refer to the studies for Article 95 BPR purposes in the meantime. Doing otherwise would mean that all negotiations should be referred to litigation or arbitration before a permission to refer to the studies may be asked from ECHA”. Further, the Prospective Applicant states that “[the Other Party’s] proposal to start an arbitration is yet another attempt to gain time, ostensibly in a ‘constructive’ way but in reality with the net effect of keeping [the Prospective Applicant] out of the market”.</i></p> <p><i>The Other Party expresses its view that “[m]aking every effort in a negotiation is not only a function of how fast one replies to emails, but also [...] of how one replies, in terms of content”. Furthermore, the Prospective Applicant states that the Other Party “has been very good at creating discussions over series of points without moving from its position, whereas [the Prospective Applicant] has always made constructive proposals [...] in order to bridge gap between the two offers”.</i></p> <p><i>Regarding the justifications of the study costs which the Other Party has provided, the Prospective Applicant states that the Other Party “has never provided any documentary evidence of how the baseline cost was determined” but “merely referred to the fact that studies were performed a long time ago and invoices were no longer available, and on that basis, applied unilaterally an ‘internal cost calculation’ method”. The Prospective Applicant continues by stating that the Prospective Applicant has contested the Other Party’s approach and made a counter-proposal but this counter-proposal was rejected by the Other Party which kept its price offer unchanged without providing further documentary evidence. Further, the Prospective Applicant adds that “as part of its data compensation formula [the Other Party] had a 10% mark up which it presented as a ‘profit share’”. The Prospective Applicant considers that a profit mark “does not belong to data sharing under BPR which is aimed merely at avoiding the duplication of studies and dividing costs”.</i></p> <p><i>The Prospective Applicant concludes that it “take[s] note that [the Other Party’s] final (and</i></p> | |

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| | | only) 'proposal' is to defer matters to an arbitration panel, and on that basis, will seek permission to refer to the data in accordance with Article 95 BPR, leaving the price determination issue to a subsequent phase as per Article 63 BPR". | |
| 82 | 26/02/2016 | <p>The Other Party states that the individual study cost are not simply "internal cost calculations" but replacement cost which are based on "[the Other Party's] practical experience when this type of studies are performed either in contract facilities or in [the Other Party's] laboratories". The Other Party further points out that "consistency with Fleischer published evaluation has also been checked", "the itemised study costs [and] references used" as well as "the studies for which a cost lower than replacement costs was justified and those studies for which invoices were available" were included in the exchanges between the parties in March 2015. The Other Party considers its proposal to involve an independent third party to determine the replacement cost as "a concrete proposal to significantly advance the negotiations" but the Prospective Applicant has rejected the approach "without giving convincing reason". The Other Party further indicates that the assessment by the third party would take "about four weeks" and it is "the most reasonable step forward to advance the negotiations". Finally, the Other Party states that if they will still fail to reach agreement after the third party assessment "arbitration for this part could be a proposed option".</p> <p>The Other Party states that the Prospective Applicant's suggestion that the Prospective Applicant needs to pay 50 % of the assumed cost of data is not correct as the Other Party's offer represents "much less than 50 % of the assumed cost of the data, taking into account all circumstances, including without limitations the restrictions [the Prospective Applicant] offers". The Other Party also states that it has decreased factually its offer by 55 % from the offer provided on 22/10/2015 and thus the Prospective Applicant's allegation that the Other Party did not depart from its offer is misleading.</p> <p>The Other Party express its surprise that "[the Prospective Applicant] persist in accusing [the Other Party] of delaying the process". The Other Party refers to Article 63(1) BPR and points out that the parties would not have had to wait for the outcome of the arbitration once such process has been agreed and therefore the Prospective Applicant's argument is "deprived of any basis". The Other Party also states that it suggested arbitration to take place only in the situation that the parties would not have been able to agree after the third party assessment. The Other Party believes that if the parties would have been able to agree on the assessment of the replacements costs by an independent third party as suggested in October 2015, the</p> | <p>Provided to ECHA only by the Other Party</p> |

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| | | Parties would have achieved an agreement already before the end of 2015. | |

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