[redacted]

26 -11- 2015

Prospective Applicant:

[redacted]

Sent via encrypted email and registered mail

Copy to Other Party:

[redacted]

Sent via encrypted email and registered mail

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

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

Dear Ms [redacted],

On 28 August 2015, you (the Prospective Applicant) submitted to the European Chemicals Agency (ECHA) a claim concerning the failure to reach an agreement on data sharing with [redacted] (the Other Party). Due to the technical problems the related documentary evidence was submitted to ECHA only on 8 September 2015. Data sharing had been sought in the context of participation to the review program of the active substances.

To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA also requested the Other Party to provide documentary evidence regarding the negotiations. The Other Party provided the requested documentary evidence on 28 September 2015.

[redacted]

Based on the documentation supplied by both parties, ECHA has decided not to grant you permission to refer to the 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.

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,

[redacted]

Christel Musset
Director of Registration

Annexes:
Annex I: Statement of reasons regarding the assessment of the data sharing dispute
Annex II: General recommendations for further data sharing negotiations

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

STATEMENT OF REASONS REGARDING THE ASSESSMENT OF THE DATA SHARING DISPUTE

Article 63(1) of the BPR requires the Prospective Applicant(s) and the Data Owner(s) to "*make every effort to reach an agreement on the sharing of the results of the tests or studies requested*". If no agreement can be reached, Article 63(3) mandates ECHA on request to "*give the prospective applicant permission to refer to the requested tests or studies on vertebrates, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred*". On this basis, ECHA conducts an assessment serving to establish whether the parties have fulfilled their legal obligation to make every effort to share the studies and their related costs in a fair, transparent and non-discriminatory way.

While the discussions between the Prospective Applicant and the Other Party on the sharing of data to submit and support applications for [redacted] predate the entry into operation of the BPR, this assessment only takes into account the period between 1 September 2013 and 28 August 2015, i.e. from the entry into application of the BPR until the submission of the dispute claim to ECHA, and it is based on the information provided by the Prospective Applicant and the Other Party.

Factual background

The Parties concluded a conditional data sharing agreement on 22 September 2014[1]. The Agreement and the Access Rights granted under it were made "*conditional upon the acceptance of all the Data [subject to the Agreement] by the Rapporteur Member state in support of the [redacted] dossier submitted by the Grantee [Prospective Applicant] within the context of the programme of work for the gradual review of existing active substances [...]*". Without such acceptance before 1 September 2015, the Agreement would not have commenced and it would have been "*null and void*". However, the Agreement contained an additional clause which gave the Prospective Applicant the right to unilaterally waive the conditionality before 1 September 2015 and pay the "*Data Compensation Price*" for some or all of the Data. Then, the Agreement would have commenced for those Data.

The Parties sent on 26 September 2014 a joint letter[2] to the Rapporteur Member State (RMS) that they had reached a data sharing agreement which is conditional upon the confirmation by the RMS that studies subject to the agreement are "*accepted for use in support of the [redacted] dossier submitted by [the Prospective Applicant] to [the RMS] for purposes of the EU review programme of existing active substances*".

[1] Cf., [redacted] Data Sharing Agreement (DSA) signed on 22 September 2014.
[2] Cf., Joint letter of the parties dated 26 September 2014.

Discussions between the Parties resumed on 4 March 2015 when the legal counsel of the Prospective Applicant contacted the legal counsel of the Other Party[3]. He stated that he had been informed by the RMS that it was not able to respond to their joint letter of 26 September 2014 because the Other Party had not sent certain information to the RMS and therefore the RMS had not been able to conclude the assessment. The legal counsel of the Prospective Applicant reminded the legal counsel of the Other Party that the "*correct implementation of this [data sharing] agreement requires both companies to do what is necessary to enable the [RMS] to make this assessment urgently*", and asked to update them and to confirm the situation by 15 March 2015.

The legal counsel of the Other Party replied to the legal counsel of the Prospective Applicant on 9 March 2015[4] informing that the RMS had requested from the Other Party one particular study report ("[redacted] to be able to carry out the Technical Equivalence (TE) assessment. The Other Party had hoped to be able to submit the study report during the previous month but it had been delayed due delays at the laboratories. The Other Party expected the study report to be available in June 2015.

The legal counsel of the Prospective Applicant proposed to the legal counsel of the Other Party on 10 March 2015[5] that the Parties would "*extend by common agreement the deadline set in [...] the Agreement to nine months after [the Other Party]'s submission of the required data to the [RMS]*". The legal counsel of the Other Party replied on 19 March 2015[6] stating that they "*cannot see that there is an issue that requires an amendment to the [...] DSA*".

The Other Party updated the Prospective Applicant of the situation on 27 July 2015[7] stating that they had submitted the requested study report to RMS on 13 July 2015 but it was rejected by the RMS due to the lack of validated analytical method. The Other Party further explained that they had commissioned a new study but due to the lack of laboratory capacity, it would not be available before March 2016. Furthermore, the Other Party reminded the Prospective Applicant about their possibility to unilaterally waive the conditionality of the DSA. In addition, in the letter dated 29 July 2015[8], the Other Party explained to the RMS why they do not agree with the rejection and urged the RMS "*to urgently (and by no later than 15th August 2015) give the confirmation requested*". On 6 August 2015, the Prospective Applicant expressed in their letter[9] to the Other Party that they do "*not feel sufficiently comfortable about the authorities' ultimate acceptance of the Data to waive the conditionality*" of the DSA. Due to the "*current climate of uncertainty*" and the approaching deadline of 1 September 2015, the Prospective Applicant proposed to amend DSA in such way that the Prospective Applicant would "*immediately upon signature of the amendments [...] pay [the Other Party] 10% of the agreed amount of data*

[3] Cf., Email of legal counsel of Prospective Applicant dated 4 March 2015.
[4] Cf., Email of legal counsel of Other Party dated 9 March 2015.
[5] Cf., Email of legal counsel of Prospective Applicant dated 10 March 2015 with an attached draft side letter.
[6] Cf., Email of legal counsel of Other Party dated 19 March 2015.
[7] Cf., Email of Other Party with an attached letter dated 27 July 2015.
[8] Cf., Letter of Other Party dated 29 July 2015.
[9] Cf., Letter of Prospective Applicant dated 6 August 2015.

compensation for [redacted] *[...]. In exchange, [the Other Party] will immediately issue the Letter[s] of Access. For as long as the authorities have made no decision on the applicability of the Data, [the Prospective Applicant] will pay an additional 10% of the data compensation price in each subsequent year on the anniversary date of the amendment, for a maximum of nine years. All payments made will be final and not reimbursable".* The proposed amendment further stipulated that *"[o]nce some or all of the Data is deemed applicable to [the Prospective Applicant]'s sources of active substances, the Parties will revert to the payment schedule of the original data sharing agreement[s], immediately paying any remaining balance of the first instalment (that is to say, after subtracting any amounts already paid), transferring the agreed amount of PBO and paying subsequent instalments according to the payment schedule [...] of the Agreement[s]".* Finally, they announced that in case the Other Party would not reply by 20 August 2015, they *"will assume that the agreements will lapse on 1 September 2015 and will proceed to request from ECHA permission to refer to [the Other Party's] data according to Article 63(3) BPR."*

The legal counsel of the Other Party replied to the letter from the Prospective Applicant on 19 August 2015[10]. He reminded that the Prospective Applicant has possibility to *"activate"* the DSA and get access to the data by paying the agreed first instalment of 50% of the data compensation price. Furthermore, he pointed out that the DSA would also commence if the RMS will confirm before 1 September 2015 that the data of the Other Party is applicable for use in support of the dossier of the Prospective Applicant. Finally, the legal counsel of the Other Party expressed their position that the Other Party has fulfilled all of its obligations under the DSA. However, the legal counsel expressed the willingness of the Other Party, in the event the DSA commence, to provide the LoA in shorter time than agreed in the DSA, i.e. within 3 working days.

In the reply[11] to the letter of the legal counsel of the Other Party, the Prospective Applicant stated that *"none of the justifications offered by [the Other Party] for its rejection of [the Prospective Applicant]'s proposal is convincing".* He asked the Other Party to *"reconsider your [Other Party's] negative response urgently, by 25 August 2015, so that an amended agreement can be finalized before the end of this month".* Furthermore, the Prospective Applicant indicated that if no amicable solution is found shortly, they would *"be forced to request from ECHA permission to refer to [the Other Party]'s data in accordance with Article 63(3) BPR".* Finally, they expressed their willingness to continue the negotiations even if they would submit a dispute claim. They, however, stated the basis for the negotiations will be different, and they will also want to reassess the compensation amount.

The legal counsel of the Other Party replied to the letter of the Prospective Applicant four days later[12] with a conclusion that the Other Party *"cannot agree with any of the arguments made by [the Prospective Applicant] in its 20 August 2015 letter, and therefore it maintains its position that it cannot accept the 6 August 2015 amendments proposed by [the Prospective Applicant] to [...] data sharing agreement[s]".* However, the legal counsel of the

[10] Cf., Letter of legal counsel of Other Party dated 19 August 2015.
[11] Cf., Letter of Prospective Applicant dated 20 August 2015.
[12] Cf., Letter of legal counsel of Other Party dated 24 August 2015.

Other Party expressed the willingness of the Other Party to extend the deadline set in the DSA to 1 September 2016, with the possibility of further reasonable extension, if necessary.

On 27 August 2015 the Prospective Applicant informed the Other Party about their intension to file a data sharing dispute claim to ECHA. The claim was filed on 28 August 2015.

Assessment

In order to comply with their legal obligation to make every effort to reach an agreement, ECHA expects the parties to negotiate the sharing of data and related costs as constructively as possible. The parties shall make sure that the negotiations move forward and therefore (i) take up relevant arguments and concerns; (ii) justify their requests; (iii) accommodate the special needs of the other party. Furthermore, parties need to be consistent in their negotiation strategy, i.e., the issues already agreed should not be reopened for discussion, unless justified.

ECHA notes that the Parties made considerable efforts to overcome disagreements on several issues. Thanks to these efforts, the Parties were able to conclude a conditional data sharing agreement in September 2014. It is apparent from the provided documentary evidence that the content of the Agreement and conditions included in it were accepted by both Parties; this is manifest in both Parties' signature to this Agreement. However, the Agreement did not come into effect because the conditions were not fulfilled, i.e., the RMS did not confirm that the data could be used for the Prospective Applicant's substance. At the same time, the Prospective Applicant did not use its explicit right to unilaterally waive the conditionality of the Agreement, i.e., the Prospective Applicant did not pay the first instalment of the Data Compensation Price before the prior confirmation by the RMS.

The Prospective Applicant expressed in March 2015 their concern about the fulfilment of the condition before the deadline set in the Agreement and proposed an extension to the deadline. At that time, the Other Party did not see any reasons to extend the deadline. However, the willingness of the Other Party to provide the LoA in the shorter time than what was stipulated in the Agreement, as proposed in the letter of 19 August 2015, shows efforts from their side to accommodate the Prospective Applicant's concerns and therefore to reach an agreement.

On 24 August 2015, when the deadline set by the Parties in the Agreement, i.e. 1 September 2015, was imminently approaching and it had become obvious that the conditions set in the Agreement would not materialise within the set timeframe, the Other Party proposed to extend the deadline by one year. With this, the Other Party agreed to the proposal made earlier by the Prospective Applicant to extend the deadlines given the pending confirmation by the RMS that the Other Party's data would be usable. This proposal of the Other Party to extend the deadline shows clear efforts from their side as the concern of the Prospective Applicant was addressed and their earlier proposal was agreed.

The Prospective Applicant did not react to this proposal, which shows lack of efforts from their side. Further, instead of agreeing to extend the deadline in the Agreement, the Prospective Applicant insisted to change the payment scheme. An extension of the deadline

could have allowed the fulfilment of the condition as agreed between the Parties in the Agreement and the Agreement would not have become null and void. Requesting the amendment for the payment scheme did not address the main concern of the Prospective Applicant, i.e., the imminent expiry of the Agreement. To the contrary, by introducing a new topic into the discussions, the Prospective Applicant did not bring the Agreement closer to the conclusion but instead reopened the negotiations and put into question the previously found compromise. The attempt to reopen the negotiations on an unrelated item which had been agreed upon between the Parties a few weeks before the jointly agreed deadline is counterproductive and therefore it is a further indication of a lack of efforts.

The Other Party acknowledged the request of the Prospective Applicant to change the payment scheme and requested a justification for such a change. The Prospective Applicant did not, however, provide any substantiated justification. This again is a demonstration of lack of efforts from the side of the Prospective Applicant.

Taking into consideration the above, ECHA concludes that the Other Party made efforts to fulfil the condition and avoid the situation that the Agreement would become null and void whereas the Prospective Applicant requested to reopen the negotiations on an essential negotiation point last moment and decided not to use their right to waive the conditionality of the Agreement. Therefore, the Prospective Applicant did not comply with their obligation to make every effort to reach an agreement. The failure to comply with this obligation leads to ECHA not granting the permission to refer.

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

GENERAL RECOMMENDATIONS FOR FURTHER DATA SHARING NEGOTIATIONS

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

- 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 their related costs.

- Technical equivalence (TE) is not a legal requirement for data sharing under BPR. TE will be required for the eventual application for product authorisation. However, in order to obtain an indication whether the data obtained will be relevant for the product authorisation, a prospective applicant may wish to make data sharing conditional upon a prior assessment of TE, i.e. chemical similarity by an independent third party. For instance, ECHA provides for the chemical similarity check service as an additional service.

- Each party shall give reasonable time to the other party for providing appropriate answers to its questions;

- Making every effort to find an agreement means that the parties exhaust their means to find an agreement;

- Making every effort in reaching an agreement requires both the prospective applicant(s) and the data owner(s) to find alternative solutions to unblock the negotiations and to be open and proactive in their communications with the other party. In case a party receives an unsatisfactory reply, which it considers unclear, invalid or incomplete, it is the responsibility of the recipient to challenge that answer, by addressing constructive, clear and precise questions or arguments to the sender;

- The negotiating parties need to be reliant, consistent and open in all negotiations. Reopening the negotiations without a well-grounded reason on an item, on which a compromise or an agreement has been already reached, is not beneficial for the progressing the negotiations.

- Any compensation for data sharing, which can be considered not to be determined in a fair, transparent and non-discriminatory manner, should be challenged without delay requiring clarification and substantiation for the requested compensation;

- If the future data sharing negotiations would fail, the Prospective Applicant is free to submit another claim, covering the efforts subsequent to the present decision.

- ECHA is never a party in the negotiations. Therefore, all arguments have to be communicated between both parties directly.