[redacted]

26 -11- 2015

Prospective Applicant:

[redacted]

Sent via encrypted email and registered mail

Copy to Data Owner:

[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	[redacted]

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. ECHA requested on 11 September 2015 further clarification on the scope of the dispute claim and received on the same date clarification that the claim concerns [redacted]. Data sharing had been sought for an application to be included on the Article 95 list.

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

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*". For submissions relating to the inclusion on the "Article 95"-list, Article 95(3) extends the scope "*to all toxicological, ecotoxicological and environmental fate and behaviour studies*" for active substances included in the Review Programme. 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.

While the discussions between the Prospective Applicant and the Other Party on the sharing of data for [redacted][1,2] 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[3]. The Agreement and the Access Rights granted under it were made "*conditional upon confirmation: a. by the Rapporteur Member State for* [redacted] *that it considers that all the Data [subject to the Agreement] are accepted for use in support of the* [redacted] *dossier that may be resubmitted by [the Prospective Applicant] for the purposes of the EU biocidal products review programme of existing active substances [...] or b. by ECHA upon an application that may be filed by [the Prospective Applicant]that the* [redacted] *marketed by the [the Prospective Applicant]is technically equivalent to the* [redacted] *(CAS number* [redacted]*), as defined in Commission Directive* [redacted]*/EU of* [redacted] *[...], whichever comes first before 1 September 2015*". Without such confirmation 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] The active substance names [redacted] and [redacted] are used in the negotiations and in this decision interchangeably.
[2] [redacted], Assessment Report. March 2013. [redacted]
[3] Cf., [redacted] Data Sharing Agreement signed on 22 September 2014.

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.

Discussions between the Parties resumed in April 2015 when the Parties sent to ECHA an application[4] asking for "*a determination of the Technical Equivalence of [the Prospective Applicant]'s* [redacted] *with regard to the established reference source of* [redacted] *in Commission Directive* [redacted] */EU of 18 July 2013*". They also informed that they had reached a data sharing agreement which is "*explicitly conditional upon the confirmation by ECHA of the Technical Equivalence*".

On 6 August 2015, the Prospective Applicant expressed in their letter[5] 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 data sharing agreement (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 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 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[6]. He reminded that the Prospective Applicant has the 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 before 1 September 2015 "*the RMS confirms that [the Other Party]'s* [redacted] *data are acceptable to be used in support of the* [redacted] *dossier that may be resubmitted by [the Prospective Applicant]*" or if "*ECHA confirms that the* [redacted] *sourced from [the Other Party] is technically equivalent to the* [redacted] *sourced from [the Prospective Applicant]*". Furthermore, the legal counsel of the

[4] Cf., Joint Application of the Parties dated 10 April 2015. The document provided to ECHA in context of this dispute claim contains only the signature of the Other Party with a place holder for the signature of the Prospective Applicant.
[5] Cf., Letter of the Prospective Applicant dated 6 August 2015.
[6] Cf., Letter of the legal counsel of the Other Party dated 19 August 2015.

Other Party noted that the Prospective applicant had actioned the application for Technical Equivalence to ECHA and that the Other Party "*had assisted [the Prospective Applicant] in this respect by co-signing the letter*". Finally, the Other Party's legal counsel expressed their position that the Other Party has fulfilled all of its obligations under the DSA. However, he expressed the willingness of the Other Party to extend the deadline set in the Agreement by three months if the Prospective Applicant demonstrates that "*its late request for technical equivalence (in April 2015), or the delay in ECHAs delivery of the outcome of the technical equivalence check, are due to an unforeseen circumstance outside the control of [the Prospective Applicant] (and making a timely commencement of the DSA impossible)*".

In the reply[7] to the letter of the legal counsel of the Other Party, the Prospective Applicant stated that "*a mere extension of the DSAs [...] and this only for a very short period of three months, is unhelpful*". The Prospective Applicant concluded 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 [the 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 that the basis for the negotiations will be different, and they will also want to reassess the compensation amount due to "*the extra costs and efforts of a mandatory data sharing procedure*".

The legal counsel of the Other Party replied to the letter of the Prospective Applicant four days later[8] 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 the [...] data sharing agreement[s]*". However, the legal counsel of the Other Party expressed the willingness of the Other Party to extend the deadline set in the DSA to 1 March 2016.

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 each other's special needs. Furthermore, parties need to be consistent in their negotiation strategy, i.e., the issues already agreed should not be reopened for discussion, unless justified.

[7] Cf., Letter of the Prospective Applicant dated 20 August 2015.
[8] Cf., Letter of the legal counsel of the Other Party dated 24 August 2015.

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., neither did the RMS confirm that the data for [redacted] could be used for the Prospective Applicant's substance nor did ECHA confirm that the [redacted] marketed by the Prospective Applicant is technically equivalent to the [redacted] as defined in Commission Directive [redacted]/EU of 18 July 2013. 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 or by ECHA.

The Prospective Applicant expressed on 6 August 2015 their concern about the fulfilment of the condition before the deadline set in the Agreement. The Other Party proposed to extend the deadline in their letter dated 19 August 2015 by three months and then in their letter dated 24 August 2015 by six months. With this, the Other Party showed clear efforts from their side to address the Prospective Applicant's concerns.

The Prospective Applicant did not agree with the proposal to extend the deadline by three months and they did not react to the later proposal to extend the deadline by six months. However, an extension of the deadline would 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. This shows a lack of efforts from their side.

ECHA also notes that the Prospective Applicant is under the obligation to comply with the Article 95 requirements and that waiving the conditionality of the DSA would have contributed to the completing of their application for inclusion on the Article 95 list.

Instead, the Prospective Applicant insisted on changing the payment scheme. Requesting the amendment for the payment scheme did not address the main concern of the Prospective Applicant, i.e., the imminent expiry of the contractual and regulatory deadline. 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 at last moment on an unrelated item which had been agreed upon between the Parties 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 to use neither their right to waive the conditionality of the Agreement nor to accept or further discuss the compromise proposals made by the Other Party. 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 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.