

██████████  
26 -11- 2015

Prospective Applicant:

██████████  
██████████  
██████████  
██████████

**Sent via encrypted email and registered mail**

Copy to Data Owner:

██████████  
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**Sent via encrypted email and registered mail**

Reference number of the dispute claim	DSH-63-3-██████████ 2015
Decision number	DSH-63-3-D-██████████ 2015
Name of active substance	██████████
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 ██████████,

On 28 August 2015, you (the Prospective Applicant) submitted a claim concerning the failure to reach an agreement on data sharing with ██████████ (the Data Owner) as well as the related documentary evidence to the European Chemicals Agency (ECHA). 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 ██████████. 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 Data Owner to provide documentary evidence regarding the negotiations. The Data Owner 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 Data Owner 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,



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. The assessment is based on the information provided by the Prospective Applicant and the Data Owner.

*Factual background*

The Prospective Applicant initiated the data sharing negotiations on the studies [REDACTED], [REDACTED] and [REDACTED] as well as [REDACTED] or alternatively [REDACTED] with their letter dated 21 August 2015. In this letter they requested a Letter of Access (LoA) to the data submitted by the Data Owner in support of the Annex I inclusion of [REDACTED]. The Prospective Applicant set the deadline for receiving the reply from the Data Owner to 27 August 2015 "in view of Article 95(2) BPR and the deadline of 1 September 2015". The legal counsel of the Data Owner replied to the letter on 25 August 2015 stating that "[a]lthough [Data Owner] would be happy to engage with [Prospective Applicant] in response to this, [...] the deadline of 27 August 2015 is, even with diligent efforts of the part of [Data Owner] not practicable" because the Data Owner must "research and collate its own historical costs for the studies concerned" and possibly "seek replacement cost quotations", consider "the data compensation formula proposed" and "the sweat equity invested in these studies" and in addition "discussion will have to take place between a large number of persons". Finally, the representative of the Data Owner indicated that they will "research the study costs, evaluate the appropriate data compensation formula, and prepare a response to the [Prospective Applicant]'s letter [...] within the next few weeks". On 28 August 2015 the Prospective Applicant informed the Data Owner that they were going to "lodge an application to ECHA for permission to refer to ecotoxicological and environmental fate data" of the negotiated substance on the same day. Indeed, the Prospective Applicant submitted the dispute claim to ECHA on 28 August 2015.

### Assessment

ECHA expects the parties to negotiate the sharing of data and related costs as constructively as possible to make sure that the negotiations move forward by, among others, initiating the negotiations sufficiently early. Furthermore, each party shall give reasonable time to the other for providing appropriate answers to its questions.

The Prospective Applicant sent to the Data Owner their first request for sharing the studies subject to this dispute claim on 21 August 2015, i.e. less than two weeks before regulatory deadline of 1 September 2015. ECHA points out that the data sharing negotiations can be a complicated process where the parties have to identify their respective data requirements and find an agreement on the costs of the data and the modalities of sharing. This typically requires more than two weeks. ECHA generally considers that negotiations should be initiated early enough before the upcoming regulatory deadline in order to allow for ample time for negotiations.

The Data Owner replied swiftly to the letter from the Prospective Applicant stating the reasons for not being able to provide the requested information by the deadline set by the Data Owner. In the same letter, the Data Owner promised to prepare a proposal for the cost sharing within the following few weeks. This is considered as an effort of the Data Owner to advance the negotiations.

Instead of waiting for Data Owner's proposal, the Prospective Applicant submitted a dispute claim to ECHA on 28 August 2015, i.e. one week after they had initiated the negotiations.

The Prospective Applicant first contacted the Data Owner regarding the studies subject to this dispute only a week before filing the dispute. Given the briefness of the negotiations the Data Owner cannot be held responsible for the parties not reaching an agreement on sharing of the data.

Taking into consideration the initiation of the negotiations less than two weeks before the regulatory deadline and the short duration of the negotiations, ECHA concludes that the Prospective Applicant did not comply with their obligation to make every effort to find an agreement. The failure to comply with this obligation leads to ECHA not granting the permission to refer.

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



**Annex II to decision DSH-63-3-D-██████████2015****GENERAL RECOMMENDATIONS FOR FURTHER DATA SHARING NEGOTIATIONS**

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

- 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;
- 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 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 must be communicated between the parties directly.