

Prospective Applicant:

14-07-2015

**Sent via encrypted email and registered mail**

Copy to Data Owner:

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Reference number of the dispute claim	DSH-63-3-[REDACTED]-2014
Decision number	DSH-63-3-D-[REDACTED]-2014
Name of active substance disputed	[REDACTED]
EC number of the substance disputed	EC [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 23 December 2014, you (the Prospective Applicant) submitted a claim concerning the failure to reach an agreement on data sharing with [REDACTED] (the Data Owner) 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 Data Owner to provide documentary evidence regarding the negotiations. The Data Owner provided the requested documentary evidence on 27 January 2015.

**Based on the documentation supplied by both parties, ECHA has decided to grant you permission to refer to certain studies requested from the Data Owner for the above-mentioned active substance.**

On 26 March 2015, ECHA requested you to provide a proof of payment; the proof of payment was provided on 13 July 2015 and amounted to [REDACTED] €. ECHA has no competence to determine the appropriateness of the "share of the cost", which may eventually be subject to the assessment of a competent national court.

The permission to refer concerns the studies indicated in Annex I to this decision. The statement of reasons of this decision is set out in the 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,

 Andreas HERDINA  
Director

Geert Dancet  
Executive Director

Annexes:

- Annex I: List of studies subject to the dispute, to which ECHA grants the permission to refer
- Annex II: Statement of reasons regarding the assessment of the data sharing dispute

[REDACTED]

**Annex I to decision DSH-63-3-D [REDACTED]-2014**
**LIST OF STUDIES SUBJECT TO THE DISPUTE, TO WHICH ECHA GRANTS THE PERMISSION TO REFER**
**Scope of the dispute:**

all data submitted for the active substance [REDACTED]

**Scope of permission to refer:**

(i) all data involving tests or studies on vertebrates for the active substance [REDACTED] (Article 63(3) of BPR)

(ii) all toxicological, ecotoxicological and environmental fate and behaviour studies relating to the active substance [REDACTED], including any such studies not involving tests on vertebrates (Article 95(3) of BPR)

Reference	Title of study	Tests on vertebrates (Yes/No)	Applicability of extension by Article 95(3) (Yes/No)	Permission to refer granted by ECHA (Yes/No)
[REDACTED]	[REDACTED]	No	No	No
[REDACTED]	[REDACTED]	No	No	No
[REDACTED]	[REDACTED]	No	No	No
[REDACTED]	[REDACTED]	No	No	No
[REDACTED]	[REDACTED]	No	No	No



Reference	Title of study	Tests on vertebrates (Yes/No)	Applicability of extension by Article 95(3) (Yes/No)	Permission to refer granted by ECHA (Yes/No)
		No	No	No
	Re	No	No	No
		No	Yes	Yes
		Yes		Yes
		Yes		Yes
		No	Yes	No <sup>1</sup>
		Yes		Yes
		Yes		Yes
		Yes		Yes

<sup>1</sup> As per our previous communication with reference DSH-63-3-2014/C5/OP4, due to a clerical error, an earlier version of this document erroneously indicated that a permission to refer would be granted to this endpoint.

Reference	Title of study	Tests on vertebrates (Yes/No)	Applicability of extension by Article 95(3) (Yes/No)	Permission to refer granted by ECHA (Yes/No)
	[REDACTED]			
[REDACTED]	[REDACTED]	No	Yes	Yes

**Annex II to decision DSH-63-3-D [REDACTED]-2014****STATEMENT OF REASONS OF THE DECISION 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 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, 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. The assessment is based on the information provided by the Prospective Applicant and the Data Owner.

*Factual background*

The Prospective Applicant sent on 25 November 2014 an email to the Data Owner in which they expressed their wish to start negotiations on data sharing. A delivery receipt of this email was received by the Prospective Applicant on 25 November 2014. This letter was also mailed to the Data Owner by registered post with acknowledgement of receipt on 26 November 2014. The registered letter was received by the Data Owner on 8 December 2014.

On 8 December 2014 the Prospective Applicant emailed to the Data Owner an "updated request". In that "updated request" the Prospective Applicant extended the list of the requested studies explaining that this was due to new information which came up in a meeting they had with the French Competent Authorities. A read receipt of this email was received by the Prospective Applicant on the same date. This "updated request" letter was also posted to the Data Owner by registered mail with acknowledgement of receipt. The letter was received on 10 December 2014.

In their initial letter of 25 November 2014 the Prospective Applicant indicated that "due to the regulatory timelines, [the Prospective Applicant] will inform ECHA about the progress of this data sharing process from December 7<sup>th</sup>, 2014. [The Prospective Applicant] would be pleased having reached an agreement with the company [Data Owner] by this date."<sup>2</sup> In their second communication they established a deadline for agreeing of 17 December 2014<sup>3</sup>, referring to the same reasons.

On 23 December 2014 the Prospective Applicant informed the Data Owner by email about their intention to submit a dispute claim to ECHA. In the same email the Prospective Applicant asked the Data Owner to contact them "as soon as possible to discuss the conditions for the sharing of the protected data related to [REDACTED] as a biocide". The dispute claim was filed to ECHA on the same date.

The Data Owner did not reply to any of the requests sent by the Prospective Applicant.

<sup>2</sup> Cf. the Prospective Applicant's letter emailed on 8 December 2014, posted on 6 December 2014 and delivered on 10 December 2014

<sup>3</sup> Cf. the Prospective Applicant's letter emailed on 25 November 2014, posted on 26 November 2014 and delivered on 8 December 2014

<sup>4</sup> Cf. the Prospective Applicant's letter emailed on 8 December 2014, posted on 6 December 2014 and delivered on 10 December 2014

<sup>5</sup> Cf. the Prospective Applicant's email of 23 December 2014

### Assessment

Making every effort to reach an agreement means that the parties negotiate the sharing of data and related costs as constructively as possible to make sure that negotiations move forward by being open and proactive in their communications, replying and asking relevant questions in a timely manner. Making every effort means, in particular, that the data owner has to react to the request by the prospective applicant and cannot ignore it.

ECHA recognises the efforts of the Prospective Applicant to initiate the negotiations with the Data Owner by the means of registered mails as well as emails. When it had not received a reply by the Data Owner to their first communication requesting Letter of Access to a list of studies by the given deadline, the Prospective Applicant sent a follow up communication with their "updated request". This shows further efforts by the Prospective Applicant to enter into negotiations, it is reasonable to expect that in case a party is slow in replying the other party sends a follow up communication to remind the other party of their pending request.

Based on Article 95(2) BPR, a data owner shall recognise that a prospective applicant must be on the list established by ECHA under Article 95 of the BPR by 1 September 2015. The negotiations should therefore be concluded soon enough for the prospective applicant to submit an application in order to be included in the list by that date, taking also into account that the assessment of applications by ECHA normally takes a few months. As the present negotiations were initiated for the purposes of Article 95 of the BPR, in the light of the upcoming regulatory deadline, it is considered that the requests made by the Prospective Applicant were timely.

ECHA notes, on the other hand, that the Data Owner ignored all the requests of the Prospective Applicant. This thereby showed a lack of efforts by the Data Owner as it is required that the data owner acts in a proactive, informative and responsive manner towards the prospective applicant in the negotiations. In the context of Article 95 of the BPR data owners can expect to be approached by a prospective applicant and should therefore be prepared accordingly, as both parties should be aware of all the regulatory timing that is applicable.

Data sharing negotiations can be a complicated process, where the parties have to identify their data requirements and find an agreement on the costs of the data and the modalities of sharing. ECHA notes that the timeline for agreement proposed by the Prospective Applicant may not have been practical. Making every effort means nevertheless, and in particular, to respond to the other party's initial request in a timely manner. If a swift substantial reply is not possible for some reasons, as a minimum effort, and due to the time pressure in the present case, it is required to acknowledge the request and indicate a reasonable timeline for a reply, taking also into consideration the regulatory deadlines that the other party is obliged to meet.

Even if the Data Owner would have not received the initial email of 25 November 2014, later correspondence was referring to it. Within that time, the Data Owner has thus been made aware of the fact that a request for data sharing was made by email on 25 November 2014, and that the Prospective Applicant was expecting a reply. However, the Data Owner did not reply to the request or send a holding reply, neither did it after the subsequent communications.

The obligation to make every effort to reach an agreement equally applies to the prospective applicant and the data owner. The absence of such effort by the Data Owner

demonstrates that it did not contribute in the data sharing negotiations, and therefore prevented negotiations even from beginning.

Based on the above, ECHA concludes that the Data Owner did not make any effort to share the data whereas the Prospective Applicant made every effort to enter into data sharing negotiations with the Data Owner to eventually reach an agreement on the sharing of the data.

As a closing remark, 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 negotiate in order to reach an agreement that will be satisfactory for both parties.



"ECHA reminds you that following Article 16 of Regulation (EC) No 1049/2001, the documents attached are subject to copyright protection."