

[REDACTED]
Helsinki, 31 May 2017

[REDACTED]

Copy to:

[REDACTED]

Decision number:
Dispute reference number:
Name of the substance:
EC number of the substance:

[REDACTED]

DECISION ON A DISPUTE

a. Decision

Based on Article 30(3) of Regulation (EC) No 1907/2006 ('REACH Regulation'),
ECHA does not grant you the permission to refer to the information you requested from the Existing Registrant, [REDACTED], [REDACTED], [REDACTED], of the above-mentioned substance.

The reasons of this decision are set out in Annex I. Advice and further observations are provided in Annex II and the factual background of the dispute is described in Annex III.

b. Procedural history

On 7 March 2017, you ('the Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with [REDACTED] ('the Existing Registrant') as well as the related documentary evidence to ECHA. To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA also requested the Existing Registrant to provide documentary evidence regarding the negotiations. The Existing Registrant submitted the documentary evidence on 27 March 2017.

c. Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to the Board of Appeal of ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under <http://echa.europa.eu/web/guest/regulations/appeals>.



Yours sincerely,

Christel Schilliger-Musset¹

Director of Registration

¹ As this is an electronic document, it is not physically signed. This decision has been approved according to the ECHA's internal decision-approval process.

Annex I: REASONS OF THE DECISION

Article 30(1) of the REACH Regulation sets out as a pre-requisite that SIEF *'participant(s) and the owner [of the data] shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way'*. In case of a dispute on the sharing of studies involving vertebrate animal testing which have already been submitted to ECHA by another registrant, Article 30(3) of the REACH Regulation requires ECHA to determine whether to grant the claimant a permission to refer to the information contained in the registration dossier, i.e. to the relevant studies. In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the documentary evidence on the negotiations as provided by the parties, to establish whether the parties have made every effort to reach an agreement on the sharing of studies and their costs in a fair, transparent and non-discriminatory way.

Summary of factual background

The Claimant initiated negotiations with the Existing Registrant for the disputed substance on 14 February 2014. There was a gap of two years in the negotiations: On 11 March 2014 the Claimant stated that they would get back to the Existing Registrant². They did so on 22 February 2016 and asked for the current price of a letter of access for [REDACTED]³.

On 29 February 2016, the Existing Registrant offered the Letter of Access (LoA) to the Claimant for the price of one third of the total costs of the dossier since there was one registrant in addition to the negotiating parties, i.e. [REDACTED] EUR.⁴ On 1 March 2016, the Claimant asked for *'composition of the total fee'*.⁵ In the absence of a reply the Claimant contacted the Existing Registrant again eight months later on 16 November 2016. The Existing Registrant then provided a cost breakdown⁶.

The Claimant requested a discount for REACH only use⁷. They also questioned the price of [REDACTED]⁸. The Existing Registrant replied by sending a revised cost breakdown and explaining that there had been errors in the previous file due to *'false shift in column E of the Excel sheet'*⁹.

On 18 January the Claimant stated that they had not found a *'discount for REACH only purpose'* in the Existing Registrant's LoA calculation and asked whether paying the LoA price would entitle them to use the data *'out of REACH registration'*¹⁰. The Existing Registrant answered that it was not mandatory to offer such discount and that their SIEF agreement *'does not allow the use of the studies outside of REACH compliance purposes and [they] don't intend to change this'*¹¹.

The Claimant replied that Guidance on Data Sharing *'recommends a reduction of cost [...] [w]here the lead registrant imposes usage restrictions'*. Based on the recommendation of

² See document with Ref. no. 7.

³ See document with Ref. no. 8.

⁴ See document with Ref. no. 9.

⁵ See document with Ref. no. 10.

⁶ See document with Ref. no. 12.

⁷ See document with Ref. no. 13.

⁸ See document with Ref. no. 13.

⁹ See document with Ref. no. 19.

¹⁰ See document with Ref. no. 20.

¹¹ See document with Ref. no. 21.

the Guidance and *'since the [LoA] cost is really high'* the Claimant asked the Existing Registrant to reconsider a discount¹². They subsequently sent a reminder to the Existing Registrant on 21 February 2017¹³. The Existing Registrant had not answered to the reminder when the Claimant launched the dispute on 7 March 2017.

Assessment

In order to reach an agreement on fair, transparent and non-discriminatory data sharing, the parties need a common understanding of how data costs should be shared in a manner that is fair, transparent and non-discriminatory. This may require some discussion, involving asking questions, making arguments, reconsidering one's stance, and replying to the question or argument. Therefore, the obligation to make every effort also means that parties that wish to challenge a specific proposal have to either ask questions to understand the other parties' proposal better or, if they understand it, explain why they disagree with it. The Practical advice for data sharing negotiations¹⁴ instructs a negotiating party to *'communicate clearly [...] why [they] consider the price to be unfair, non-transparent or discriminatory'*. If a claimant does not make the effort of explaining why he disagrees with a proposal, but instead submits a data sharing dispute, he has not made every effort yet and not submitted the dispute as a measure of last resort.

ECHA notes that core of the dispute at hand is a disagreement on whether the LoA price should be reduced since usage of the joint submission dossier is limited to REACH compliance purposes. This point of controversy prevented the Parties from finding an agreement on the conditions for sharing the information. ECHA notes that the Parties managed to solve another issue raised in the negotiations, regarding the cost of a specific endpoint.¹⁵

The Claimant asked for a discount for 'REACH-only' use and referred to the Guidance's recommendation to reduce cost when *'lead registrant imposes usage restrictions'*. In this context, the Claimant indicated two parts of the ECHA Guidance on Data Sharing: 1) section 5.5.2. where it is stated that *'[i]t is appropriate to take into account any limitation to usage conditions in the financial value assigned to a given study'* and 2) *'Example 7: Valuation with usage restrictions'*. The Claimant also asked for clarification on whether they would be able to use the data for other purposes than a REACH registration.¹⁶

In their email of 20 January 2017, the Existing Registrant replied that their data sharing agreement foresaw a right to use the data in order to comply with the REACH Regulation. They referred to the guidance and pointed out that a discount for the above-mentioned reason *'is not mandatory'*¹⁷.

The Claimant later asked for a REACH-discount again.¹⁸ However, they merely referred to the recommendation in the guidance and justified a discount with the high study costs. They did not explain why they thought a discount would be appropriate or fair.

In this situation, ECHA points out that the Claimant has not made substantial efforts to explore the fairness, the pros or cons of a REACH-only discount, which they are trying to

¹² See document with Ref. no. 22.

¹³ See document with Ref. no. 23.

¹⁴ <https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations>

¹⁵ See documents with Ref. no.'s 13. and 19.

¹⁶ See document with Ref. no. 22.

¹⁷ See document with Ref. No. 21.

¹⁸ See document with Ref. No. 22.

obtain, and the absence of which seems to be the reason for the dispute submission. In the absence of such efforts, the dispute submission was not a measure of last resort. [REDACTED]

[REDACTED]. The Claimant paused the negotiations for almost two years between 2014 and 2016²¹, [REDACTED]. ECHA lastly points out that the Claimant failed to forewarn the Existing Registrant of their intention to launch a dispute and thus did not give the Existing Registrant a chance to react on the prospect of the Claimant planning to submit a claim²³. The Guidance advises that *'dispute procedures must be initiated as a last resort, i.e. only after all the possible efforts and arguments have been exhausted and the negotiations have failed'*. This, too, indicates that the Claimant did not submit the dispute as a measure of last resort.

Based on the above, ECHA concludes that the Claimant did not make every effort in the negotiations and did not submit the dispute as a measure of last resort.

Consequently, ECHA does not grant the Claimant permission to refer to the data submitted by the Existing Registrant. Both parties are encouraged to carry on with the negotiations and to take into consideration the observations made by ECHA in the present decision. This does not exclude the possibility to submit again at a later stage a new dispute to ECHA, as a measure of a last resort.

¹⁹ See documents with Ref. no.'s 11., 14., 17., 20., 23.

²⁰ See Guidance on data-sharing, section 1.2.4.

²¹ See documents with Ref. No.'s 7. and 8.

²² See documents with Ref. No.'s 10. and 11.

²³ See document with Ref. No. 23.

Annex II: ADVICE AND FURTHER OBSERVATIONS

ECHA stresses that 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 of their related costs. Therefore, ECHA would like to make some general observations in order to facilitate a future agreement:

- Parties of data sharing negotiations should look into different options to unblock and advance the negotiations;
- They should explore what data can be used for what purposes and whether a discount or broader usage rights would be fair taking into account overall cost sharing;
- Disagreed items must be challenged with valid arguments;
- ECHA points out that correct and consistent communication between the parties involved is important so that misunderstandings can be avoided;
- ECHA is never a party in the negotiations. Therefore, all arguments have to be communicated between both parties directly. Any document, which has not been shared with the Existing Registrant, cannot be taken into consideration in ECHA's assessment of the dispute claim;
- 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;
- If the future negotiations would fail again, the Claimant is free to submit another claim, covering the efforts subsequent to the dispute claim that is the subject of the present decision.

Annex III: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

CHRONOLOGY TABLE		
Reference number	Submission date	Article
██████████	07/03/2017	30(3)

Ref. no.	Date	Content	Remark
1.	14/02/2014	The Claimant asks the Existing Registrant about the following: 1. Letter of Access (LoA) costs of the disputed substance for four tonnage bands 2. Chemical Safety Report (CSR) 3. Substance Identity Profile (SIP) and Classification & Labelling (C&L) 4. Reimbursement scheme.	
2.	19/02/2014	Claimant reminds the Existing Registrant of Ref. no. 1.	
3.	19/02/2014	The Existing Registrant promises to reply as soon as possible.	Provided only by the Existing Registrant
4.	03/03/2014	The Existing Registrant asks the Claimant for half of the costs for meeting the dossier requirements since the Existing Registrant is the only registrant of the substance. The Existing Registrant promises to recalculate costs if more registrants will join or more work is needed. They also state that possible refund will be based on principle of fair cost sharing and there is threshold of €██████████. The Existing Registrant then informs that the substance is ██████████ and the	

Ref. no.	Date	Content	Remark
		required Chemical Safety (CSA) report is included in the cost.	
5.	05/03/2014	The Claimant considers the costs ' <i>unreasonable</i> ' since they are ' <i>much more expensive than other [REDACTED] substances</i> ' and the substance is [REDACTED]. They asks for ' <i>cost list specifying the components of total costs</i> '.	
6.	07/03/2014	The Existing Registrant refers to ECHA site ²⁴ with overview of tests available for the substance. They further inform that costs are based on ' <i>Fleischer prices or actual invoices</i> '. The Existing Registrant also states that they ' <i>had to run many tests</i> ' to proof that the substance does not need to be classified. They then write that ' <i>read-across with other [REDACTED]</i> ' was impossible due to different ' <i>toxicity profiles</i> '. They justify the higher LoA cost with availability of open literature data for [REDACTED] unlike for the disputed substance and smaller number of registrants. They request written commitment on LoA payment before discussing further.	
7.	11/03/2014	The Claimant states that they have forwarded the information to their client and will get back to the Existing Registrant ' <i>accordingly</i> '.	
8.	22/02/2016	The Claimant asks for current LoA cost for [REDACTED]. They refer to the ' <i>new Regulation of data sharing</i> ²⁵ ' and ask for ' <i>calculation model</i> ' of the LoA.	
9.	29/02/2016	The Existing Registrant informs about the costs determined in [REDACTED]. They state that there now is one other registrant so LoA price is [REDACTED] of total: <ul style="list-style-type: none"> • [REDACTED] of about € [REDACTED] = about € [REDACTED] 	

²⁴ <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

²⁵ http://echa.europa.eu/view-article/-/journal_content/title/reach-data-sharingprinciples-clarified

Ref. no.	Date	Content	Remark
		<ul style="list-style-type: none"> • [REDACTED] of about € [REDACTED] = about € [REDACTED] • [REDACTED] of about € [REDACTED] = about € [REDACTED] • [REDACTED] of about € [REDACTED] = about € [REDACTED] <p>The Existing Registrant also writes that inflation correction will be applied and repeats the same conditions on cost recalculation, refund and threshold as in Ref. no. 3.</p>	
10.	01/03/2016	The Claimant asks for total fee of [REDACTED] with inflation correction and 'composition of the total fee € [REDACTED]'.	
11.	16/11/2016	The Claimant asks for current LoA cost for [REDACTED] and for the inflation rates. They state that they need the quotation for budget estimation and are 'awaiting for [the Existing Registrant's] reply soon'.	
12.	18/11/2016	<p>The Existing Registrant reconfirms the costs presented in Ref. no. 9 and attaches overview of the current LoA costs. First tab of the Spreadsheet lists Study costs and contains the following columns:</p> <p>[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]</p> <p>For some tests 'Based on actual invoice' is indicated as 'Reason for the different value'.</p> <p>Second tab of the Excel file contains 'Calculation of the LoA cost':</p> <p>[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]</p> <p>[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]</p>	Data Sharing agreement provided only by the Existing Registrant

Ref. no.	Date	Content	Remark
		██████████ in 2007 and that even now performing the study in lab costs less than € ██████████.	
14.	23/11/2016	The Claimant requests the Existing Registrant to reply to Ref. no. 13 since the Claimant <i>'would like to purchase the LOA and finish the registration soon'</i> .	Provided only by the Existing Registrant
15.	23/11/2016	The Existing Registrant informs that they are working on the matter and promises to reply as soon as possible.	
16.	30/12/2016	The Claimant asks for news about the LoA calculation issue because their client would like to register soon.	
17.	09/01/2017	The Claimant sends a reminder about Ref. no. 16.	
18.	09/01/2017	The Existing Registrant apologises for the delay and states that they expect to get a final version of corrected LoA costs the following Wednesday.	
19.	12/01/2017	The Existing Registrant encloses revised overview of LoA costs. They apologise for errors in the previous file due to <i>'false shift in column E of the Excel sheet'</i> . The Existing Registrant states that they have re-checked all figures and added costs of ██████████. They also promise to send the SIEF agreement when the Claimant has decided on the tonnage band.	According to the Existing Registrant dated 11/01/2017
20.	18/01/2017	The Claimant states that they have not found <i>'discount for REACH only purpose'</i> in the Existing Registrant's LoA calculation and asks the Existing Registrant to confirm that paying the LoA price entitles the Claimant to use the data <i>'out of REACH registration'</i> . In that case the Claimant wishes to sign SIEF Agreement and <i>'purchase the LOA now'</i> .	

Ref. no.	Date	Content	Remark
21.	20/01/2017	The Existing Registrant states that it is ' <i>not mandatory</i> ' to offer LoA discount for REACH purposes. The Existing Registrant further informs that their SIEF agreement ' <i>does not allow the use of the studies outside of REACH compliance purposes and [they] don't intend to change this</i> '. They then ask for the Claimant's ' <i>full details</i> '.	
22.	06/02/2017	The Claimant states that Commission Implementing Regulation (EU) 2016/9 recommends cost reduction when ' <i>lead registrant imposes usage restrictions</i> ' and refers to two parts of the Guidance on Data Sharing: 1) section 5.5.2 and 2) Example 7 on page 147. The Claimant then asks the Existing Registrant to re-consider discount for REACH only purpose ' <i>since the [LoA] cost is really high</i> '.	
23.	21/02/2017	The Claimant asks the Existing Registrant to answer to Ref. no. 22 and states that they are ' <i>awaiting for [the Existing Registrant's] reply soon</i> '.	Provided only by the Existing Registrant

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