

The Claimant

[REDACTED]

Copy to:
The Other Party

[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 grants you the permission to refer to the information you requested from the Existing Registrant, [REDACTED], of the above-mentioned substance.

According to Article 30(3) of REACH, the Existing Registrant shall have a claim on you for an equal share of the cost, which shall be enforceable in the national courts, provided that the full study report(s) is made available to you.

The reasons of this decision are set out in Annex I. An overview of the negotiations is provided in Annex II. The list of studies ECHA grants you permission to refer along with copies of (robust) study summaries can be found in Annex III and IV, respectively. Instructions on how to submit your registration dossier are provided in Annex V.

b) Procedural history

On 24 October 2016, you ('the Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with [REDACTED] ('the Other Party') 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 Other Party to provide documentary evidence regarding the negotiations by 25 November 2016. The Other Party did not however submit any evidence to ECHA. Therefore, the assessment of this dispute is based only on the documentary evidence provided

by the Claimant. When requesting the Other Party to provide its evidence ECHA made the Other Party aware that if the Other Party would not make the requested information available to ECHA, the assessment would be conducted and the decision taken solely on the basis of the evidence provided by the Claimant.

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>.

d) Advice and further observations

ECHA reminds both parties that despite of the present decision they are still free to reach a voluntary agreement. Accordingly, ECHA strongly encourages the parties to negotiate further in order to reach an agreement that will be satisfactory for both parties.

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.

Factual background

On 3 July 2015, the Other Party contacted all the SIEF members, informing that it was the Lead Registrant and asking the companies to communicate their registration intentions². On 7 July 2016, the Claimant informed the Other Party of their intention to register the substance in question for the tonnage band of ██████ t/y³.

On 30 October 2015 the Claimant asked for the cost of Letter of Access for the tonnage bands ██████ t/y and 1 ██████ t/y⁴. The Other Party communicated to the Claimant on 2 November 2015 the costs for the tonnage bands ██████ t/y, ██████ t/y and ██████ t/y⁵.

In its email to the Other Party on 11 December 2015 the Claimant wrote that it '*would like to have the details of the LoA cost calculation. There is no detailed information [about it] in the SIEF agreement*'⁶. In the absence of any reply from the Other Party to this email, the Claimant asked again for the detailed costs on 9 February 2016⁷. Later on the same day, the Other Party promised to provide an answer by 15 February 2016⁸.

The Other Party did not get back to the Claimant by the above-mentioned date. On 24 February 2016 the Claimant asked if the Other Party had '*any update to provide on the detailed LoA cost*'⁹. The Other Party replied on 26 February 2016 and informed that it as the Lead Registrant had received a final decision on a compliance check from ECHA and it needed to submit further information for ██████ endpoints. In the same email of 26 February 2016, the Other Party updated the Letter of Access price for ██████ t/y '*including the further cost by performing the mentioned test requested by ECHA*'. The Other Party then also provided the Claimant with a table where the costs were divided into three categories: '*Studies compensation*', '*Dossier&CSR*' and '*Admin*'¹⁰.

The Claimant replied, on the same day, that '*in fact*' it was requesting '*the detailed costs for studies compensation study by study*'¹¹. The Claimant then sent reminders to the Other Party on 10 May 2016 and 26 May 2016 and asked again for '*the itemisation and justification of*

³ See document Ref. no. 2

³ See document Ref. no. 2

⁴ See document Ref. no. 3

⁵ See document Ref. no. 4

⁶ See document Ref. no. 5. The negotiations provided to ECHA do not include any SIEF agreement.

⁷ See document Ref. no. 6

⁸ See document Ref. no. 7

⁹ See document Ref. no. 8

¹⁰ See document Ref. no. 9

¹¹ See document Ref. no. 10

data and any other costs included in the Letter of Access and *'detailed informations concerning [...] reimbursement mechanism'*. The Claimant announced on 10 May 2016 for the first time the possibility to use a data-sharing dispute if it did not receive an answer within one month¹².

The Other Party explained to the Claimant on 27 May 2016 that the Other Party was still awaiting the *'final quotation for the additional testing'* and that the *'LoA will be recalculated accordingly'*. The Other Party promised to give an answer soon¹³.

The Claimant subsequently sent requests for itemisation of the costs on 8 June 2016, 21 June 2016 and 29 June 2016¹⁴. On 30 June 2016 the Other Party promised to send information *'later today'*¹⁵.

The Claimant sent further reminders to the Other Party on 6 July 2016, 28 July 2016, 9 August 2016, 15 September 2016, 5 October 2016 and 12 October 2016 asking for the *'costs, study by study'* and emphasizing the urgency of the request¹⁶. In the emails of 5 and 12 October 2016, the Claimant wrote that they tried to contact the Other Party by phone but did not manage to reach the appropriate person and were not contacted back¹⁷. On 14 October 2016 the Claimant informed the Other Party that it would *'initiate a dispute claim to ECHA'* *'if [it] did not get and answer by October 19'*¹⁸. The Claimant submitted the related dispute claim on 24 October 2016.

Assessment

In order to agree on fair, transparent and non-discriminatory sharing of data and costs, the parties need to find a common understanding of the costs of the data. Communicating on the cost calculation is therefore a pre-requirement for successful data-sharing negotiations. Following the Commission Implementing Regulation (EC) 2016/9, a potential registrant has the right to receive a meaningful cost break down (itemisation) which links cost items with data requirements and provides a justification for each cost item. The aim of the Implementing Regulation is to facilitate fair, transparent and non-discriminatory data-sharing process by creating clearness regarding all the data to be shared. Article 2 of the Implementing Regulation therefore foresees an itemisation of all costs, past, present and future. The information provided must be detailed enough to allow the potential registrant to assess the specific need of the studies, their individual costs and the relevance of administrative costs. The Implementing Regulation specifies that this cost itemisation must be provided to the potential registrant without undue delay.

During the negotiations, the Claimant requested numerous (by email reminders and phone calls) for details of the Letter of Access cost calculation as this information was not available in the SIEF agreement¹⁹. The Claimant emphasised the necessity of having the information about the detailed costs for the studies compensation, study by study, during the entire negotiation process of almost a year.

The Other Party provided in the beginning of the negotiations the Letter of Access prices for

¹² See document Ref. no. 11, 12

¹³ See document Ref. no. 13

¹⁴ See documents Ref. no. 14, 16, 17, 18

¹⁵ See document Ref. no. 19

¹⁶ See documents Ref. no. 20, 21, 22, 23, 24, 25

¹⁷ See document Ref. no. 24, 25

¹⁸ See document Ref. no. 26

¹⁹ See documents Ref. no. 5, 6, 8, 10, 11, 12, 14, 16, 17, 18, 20, 21, 22, 23, 25, 26

the substance in question for [REDACTED] different tonnage bands²⁰. These prices did not however include any detailed cost itemisation. The only table of costs, which was received from the Other Party during the negotiations, is mentioned in an email dated 26 February 2016²¹. However, the division of the costs it shows, in three general and undefined categories without a study by study break down, could not enable the Claimant to get a clear understanding of the data to be shared, their need and their corresponding costs. The Claimant replied on 26 February 2016 that its request was for *'the detailed costs for the studies compensation, study by study'*²². The Other Party never provided detailed cost break down, despite having promised to do so several times²³.

The only explanation that the Other Party communicated for the delay to provide the cost break down was that they had received a final decision on compliance check from ECHA. The Other Party indeed indicated in an email of 27 May 2016 that they were *'waiting for the final quotation for the additional testing'*²⁴. However, this justification was not explained further and seems contradictory with the Other Party's previous email of 26 February 2016, in which it indicated that the given prices *'includ[ed] the further costs by performing the mentioned test requested by ECHA'*²⁵. Moreover, the Other Party could have provided itemisation for the data that was not affected by the compliance check decision. Furthermore, the additionally performed studies were only relevant for the [REDACTED] tonnage bands and the change of the price of the Letter of Access only affected the tonnage band [REDACTED] t/y (while the Claimant asked for cost break down for [REDACTED] t/y and [REDACTED] t/y). The compliance check decision does not justify not providing a cost break down for almost one year.

Furthermore, ECHA notes that the Other Party remained silent for almost 4 months before the launching of the dispute. The Other Party's last email of 30 June 2016 indicated that *'all information'* would be sent later on the same day²⁶. Following this email, the Other Party ignored however all the Claimant's attempts to progress with the negotiations, as well as the Claimant's mention of the urgency of registering the substance²⁷, until the Claimant launched the dispute on 24 October 2016 (after informing the Other Party of its intention²⁸).

ECHA considers that the Claimant made every effort to reach an agreement with the Other Party and to understand the Letter of Access cost. Due to the lack of reply from the Other Party on the cost itemisation for almost a year, the Claimant did not even have the ground to start the negotiations. By failing to provide a cost itemisation without undue delay, the Other Party did not fulfil an explicit obligation from the Commission Implementing Regulation (EC) 2016/9 to provide a cost break down. Therefore, the Other Party did not make every effort to reach an agreement on data sharing with the Claimant.

Conclusion

Based on the above, ECHA concludes that the Other Party did not make every effort to reach an agreement to share data. The Other Party did not provide the Claimant with a cost itemisation to enable them to assess whether the Letter of Access price is fair, transparent and non-discriminatory.

²⁰ See document Ref. no. 4

²¹ See document Ref. no. 9

²² See document Ref. no. 10

²³ See documents Ref. no. 7, 13, 19

²⁴ See document Ref. no. 13

²⁵ See document Ref. no. 9

²⁶ See document Ref. no. 19

²⁷ See documents Ref. no. 22, 23, 25, 26

²⁸ See documents Ref. no. 11, 26

Against this background, the Claimant made every effort to find an agreement and filed the data sharing dispute as a measure of last resort. Therefore, ECHA grants the Claimant a permission to refer to the [REDACTED] studies submitted by the Other Party for the [REDACTED] t/y band, which is the tonnage band indicated in the Claimant's dispute claim and which was covered by the negotiations with the Other Party²⁹. These studies are listed in Annex III to the present decision.

²⁹ See documents Ref. no. 2, 3

Annex II: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

CHRONOLOGY TABLE		
Reference number	Submission date	Article
██████████	24/10/2016	30(3)

Ref. no.	Date	Content
1.	03/07/2015	The other party contacts all the SIEF members and informs them that they are the lead registrant and ask the companies about their registration intention with deadline 20/07/2015.
2.	07/07/2016	██████████ (the Claimant) informs the Other Party of their intention to register the substance 1 ██████████ for the ██████████ t/a.
3.	30/10/2015	The Claimant asks for the Letter of Access costs for tonnage bands ██████████ t/a and ██████████ t/a.
4.	02/11/2015	The other party provides the prices for the Letter of Access for the ██████████ different tonnage bands: ██████████ euros ██████████ euros ██████████ euros

Ref. no.	Date	Content
5.	11/12/2015	The Claimant requests the details for the Letter of Access cost calculation. In particular the Claimant asks if the Other Party applies risk premium and a rebate for REACH only use.
6.	09/02/2016	The Claimant resends its request of 11/12/2015 and requests again the details of the Letter of Access costs.
7.	09/02/2016	The Other Party promises to provide the detailed Letter of Access cost and the data sharing agreement by 15/02/2016
8.	24/02/2016	The Claimant sends second reminder to the other party and asks again for the detailed Letter of Access costs.
9.	26/02/2016	<p>The Other Party replies that they as the lead registrant for the substance in question have received a final decision on compliance check from ECHA and they were requested to submit further information on [REDACTED] endpoints. For this reason the Other Party has recalculated the Letter of Access price and communicates the new price for each tonnage band:</p> <p>[REDACTED] euros</p> <p>[REDACTED] euros</p> <p>[REDACTED].</p> <p>The Other Party attaches a table with the costs divided in three categories: "Studies compensation", "Dossier&CSR", "Admin"</p>
10.	26/02/2016	The Claimant requests the details of the compensation for the studies study by study.
11.	10/05/2016	The Claimant requests again the itemisation and justification of data and any other costs included in the Letter of Access prices. The Claimant announces for the first time that they intent to use a data-sharing dispute if they do not receive an answer

Ref. no.	Date	Content
		within one month.
12.	26/05/2016	The Claimant sends another reminder and asks again for the detailed information concerning the costs of the studies.
13.	27/05/2016	The Other Party informs that they are waiting for final quotation for additional tests and will then re-evaluate the price of the Letter of Access. The Other Party states that they think "the final price will be lower" than the price communicated on 26/02/2016. The other party asks the claimant for patience and promises to give an answer soon.
14.	08/06/2016	The Claimant requests again an answer from the Other Party.
15.	08/06/2016	The Other Party promises to reply to the Claimant on 12/06/2016.
16.	08/06/2016	The Claimant asks for the information as soon as possible since they are expecting the reply since December 2015.
17.	21/06/2016	The Claimant repeats their request for information about the detailed costs study by study.
18.	29/06/2016	The Claimant reminds the other party that they are awaiting an answer since 27/05/2016 and asks again about the costs of the Letter of Access study by study
19.	30/06/2016	The Other Party apologises for the delay and promises to send information later on during the day.
20.	06/07/2016	The Claimant asks again about the costs of the Letter of Access study by study
21.	28/07/2016	The Claimant sends another reminder and asks again about the itemisation of the studies.
22.	09/08/2016	The Claimant sends another reminder and emphasizes the fact that they have tried to get information about the price of the Letter of Access since February 2016. The Claimant also states that now the registration of the substance becomes urgent.

Ref. no.	Date	Content
23.	15/09/2016	The Claimant informs the Other Party that they have tried to reach them over the phone without success. The Claimant asks for urgent feedback and emphasizes the long period they have been awaiting an answer and as well the fact that the Other Party constantly promises a reply and never sends one.
24.	05/10/2016	The Claimant informs the other party that they have spoken on the phone with two colleagues of the Other Party's contact person and they have been promised to receive a call back from the Other Party. The Claimant asks for an answer.
25.	12/10/2016	The Claimant states that they tried to call the other party one more time. The Claimant expresses once more their disappointment because they are awaiting an answer since February 2016 and they "cannot be patient anymore". The Claimant asks the Other Party to contact them and leaves phone number and email. The Claimant states that they have reviewed the SIEF agreement and they would like to proceed urgently with the registration.
26.	14/10/2016	The Claimant informs the Other Party that if they do not receive an answer by 19/10/2016, they will launch a data sharing dispute.

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