

[REDACTED]
25 -11- 2015

Addressee (Claimant):

[REDACTED]

Sent via REACH-IT

Copy to Other Party:

[REDACTED]

Sent via REACH-IT

Reference number of the dispute claim	DSH-30-3-[REDACTED] 2015
Decision number	DSH-30-3-D-[REDACTED] 2015
Name of the substance disputed	[REDACTED]
EC number of the substance disputed	[REDACTED]

DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 30(3) OF THE REACH REGULATION (EC) No 1907/2006

Dear Madam, Sir,

On 10 September 2015, [REDACTED] (hereinafter referred to as 'the Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with [REDACTED] (hereinafter referred to as 'the Other Party'), as well as the related documentary evidence to the European Chemicals Agency (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. The Other Party submitted the documentary evidence on 2 October 2015, as requested by ECHA.

Based on the documentation supplied by both parties, ECHA has decided to grant you, as the Claimant, permission to refer to certain studies requested from the Other Party for the above-mentioned substance.

The Other Party shall have a claim on you for an equal share of the cost, provided they make the full study report available to you, which shall be enforceable in the national courts according to Article 30(3) of REACH.

The permission to refer concerns the studies indicated in Annex I. The statement of reasons regarding the assessment of the data sharing dispute is set out in Annex II to this decision

while the factual background regarding the data sharing negotiations is set out in Annex III. The endpoint study records for which permission to refer has been granted for the substance with EC number [REDACTED] are provided in Annex IV. Instructions on how to submit your registration dossier after resolution of the data sharing dispute procedure are provided in Annex V.

As a remark, ECHA reminds both parties that despite of the present decision they are still at liberty 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.

In accordance with Article 30(5) of the REACH Regulation, both parties involved in the dispute may appeal against this decision 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: 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
- Annex III: Factual background regarding the data sharing negotiations
- Annex IV: Endpoint study records for which permission to refer has been granted for the substance with EC number [REDACTED]
- Annex V: Instructions on how to submit your registration dossier after resolution of the data sharing dispute procedure

Annex I to decision DSH-30-3-D- [REDACTED] 2015**LIST OF STUDIES SUBJECT TO THE DISPUTE, TO WHICH ECHA GRANTS THE PERMISSION TO REFER**

Scope of the dispute: All data submitted for the substance [REDACTED] for a registration in the tonnage band [REDACTED]

Scope of permission to refer: All data involving tests or studies on vertebrates for the substance [REDACTED] (Article 30(3) REACH) for a registration in the tonnage band [REDACTED]

Endpoint	Title of the study
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

Annex II to decision DSH-30-3-D-██████████2015**STATEMENT OF REASONS REGARDING THE ASSESSMENT OF THE DATA SHARING DISPUTE**

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, so as 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.

Making every effort to share the data and their related costs in a fair, transparent and non-discriminatory way means that the parties negotiate the sharing of data and related costs as constructively as possible to make sure that the negotiations move forward swiftly by expressing their arguments and concerns and replying to each other's questions and arguments. In particular, this requires parties to maintain a cooperative approach and be a reliable partner in the negotiations, including by being ready to act in a swift manner and ensuring that the chosen model of conducting the data sharing negotiations does not hinder their timely progress.

In the case at hand, the Claimant initiated data sharing negotiations in August 2014¹, asking for the SIEF agreement as well as for the LoA price and the underlying calculation method. However, the Other Party was only able to provide the requested information in February 2015² and March 2015³ respectively. The Other Party explained to the Claimant that the delays in providing the requested cost calculation and the SIEF agreement were due to their internal structure which would require from them, as Only Representative, to obtain prior approval from their client, *i.e.* the represented non-EU company, before providing the requested documents.⁴ Upon receipt of the cost calculation as well as of the SIEF agreement, the Claimant announced their agreement⁵ and they requested from the Other Party to proceed with the signature of the SIEF agreement⁶. The Other Party indicated that similarly to the provision of the requested cost calculation and the SIEF agreement, prior to the signature of the latter they needed to obtain the prior approval of the represented non-EU company.⁷ ECHA notes that until the dispute claim was lodged on 10

¹ See document Ref. no. 1

² See document Ref. no. 5

³ See document Ref. no. 9

⁴ See document Ref. no. 5 and 8

⁵ See document Ref. no. 7 and 10

⁶ See document Ref. no. 7

⁷ See document Ref. no. 9

September 2015 and despite the Claimant's earlier reminders⁸ the Other Party had not communicated the signed SIEF agreement to the Claimant.

The Other Party was thus not able to provide on time upon the request of the Claimant the final cost calculation and SIEF agreement, nor proceed with the signature of the agreed SIEF agreement pending the approval of the represented non-EU company. ECHA highlights that any party is both free to and responsible for establishing their internal structures and working methods. However, making every effort in sharing the data and their related costs requires from the parties to ensure that any such structure may not impede on fulfilling their obligations under REACH, including those towards the other party in data sharing negotiations.

ECHA further underlines that in accordance with Article 8 of the REACH regulation, an Only Representative is fully responsible for the compliance with any obligations of the importers stemming from that Regulation. This includes any obligations of the importers under Article 30 REACH, namely conducting and concluding data sharing negotiations.⁹

Against this backdrop, ECHA notes that by delaying the provision of the LoA cost and its cost calculation as well as the SIEF agreement and by not proceeding with the signature of the agreed SIEF agreement, the Other Party has effectively caused the failure of the data sharing negotiations and thereby failed to comply with their obligation to make every effort to come to an agreement. The Other Party, as Only Representative, was fully responsible for complying with the obligations of the importers under REACH, including making every effort in sharing the data and their related costs in a fair, transparent and non-discriminatory way. While the Other Party was free to choose the way they deemed fit for conducting the data sharing negotiations with the Claimant, the selected working method had *de facto* hindered the timely progress of the negotiations and their conclusion.

Conclusion

Based on the above, ECHA concludes that the Other Party did not make every effort to reach an agreement to share the data. In particular, the Other Party delayed providing crucial documentation and finally impeded the signature of the SIEF agreement. This constituted a failure to comply with the obligation to make every effort to reach a fair, transparent and non-discriminatory agreement on the sharing of data and their costs as required by Article 30 REACH.

Therefore, ECHA grants the Claimant permission to refer to certain data submitted by the Other Party, listed in Annex I to the present decision.

⁸ See document Ref. no. 10 and 11

⁹ See also "Guidance on Registration", chapter "2.1.2.5 Only representative of a 'non-EU manufacturer'", available at http://echa.europa.eu/documents/10162/13632/registration_en.pdf

Annex III to decision DSH-30-3-D- [REDACTED] 2015
FACTUAL BACKGROUND REGARDING THE DATA SHARING NEGOTIATIONS

Ref. no.	Date	Content	Remark
1	04/08/2014	The Prospective Applicant contacted the Other Party, informed them of their intention to register for 1-10 tpa and asked to be provided with the SIEF agreement, the cost calculation and the LoA price.	Provided by both parties
2	05/08/2014	In their reply, the Other Party informed that they were currently re-calculating the LoA costs as the initial prices had been based on the registration intentions of the SIEF members, while in the end there had been fewer registrants than foreseen. They asked for patience and promised to come back to the Claimant.	Provided by both parties
3	20/01/2015	The Claimant contacted the Other Party again and asked for an update regarding the cost calculation and the LoA price.	Provided by both parties
4	03/02/2015	The Claimant again contacted the Other Party, highlighting that they had initially gotten in touch in August 2014 and that "After several emails and phone calls we don't see any progress". They announced that if they didn't get to an agreement on the LoA, they would need to consider opting-out, which might trigger evaluation. Further, they highlighted that "The OR ([REDACTED]) is responsible for the full compliance of all studies in the main dossier". Finally, they repeated their request for the SIEF agreement and stated that it should be easy to update the cost calculation following the inclusion of a missing study.	Provided by both parties
5	06/02/2015	The Other Party replied, stating that their "hands are tied [...] due to internal difficulties". They offered to "include the approx. costs of the study into the calculation" and promised to do the final calculation "as soon as possible". Further, they provided the SIEF agreement and the SIP.	SIEF agreement provided by both parties; SIP only provided by the Other Party

Ref. no.	Date	Content	Remark
6	06/02/2015	The Claimant thanked for the information received and promised to come back to the Other Party during the following week. Further, they provided their SIP confirmation.	Message only provided by the Claimant; SIP confirmation provided only by the Other Party
7	26/02/2015	The Claimant agreed with the SIEF agreement and provided their company details to complete the contract.	Attachments only provided by the Other Party
8	09/03/2015	With reference to a recent phone call, the Other Party informed that the cost calculation had been updated following the inclusion of a missing study, and that now only the management would need to approve the updated calculation. However, due to the Chinese New Year, this would be delayed until the beginning of the next week.	Only provided by the Claimant
9	18/03/2015	The Other Party provided the updated cost calculation but informed that due to the missing consent from their client, they could not yet provide the SIEF agreement. However, discussions to get the agreement from their client to share the finale SIEF agreement were on-going.	Provided by both parties
10	18/03/2015	The Claimant informed they understood the cost calculation, and asked which open issues were pending with the Other Party's client and hindering the finalisation of the agreements.	Only provided by the Other Party
11	29/05/2015	The Claimant summarised the phone call of the previous day, reminding that the Claimant had informed the Other Party on 4 August 2014 about their intention to register. They further highlighted that the Other Party as OR was the main contact for SIEF members, regulatory authorities and potentially courts within the EU, that both parties had agreed on the SIEF agreement including the cost calculation, and that the Other Party had successfully registered for [REDACTED]. However, the Other Party refused to	Only provided by the Claimant

Ref. no.	Date	Content	Remark
		<p>finalise and sign the agreement due to their client's unwillingness to proceed with the signature. However, there were other joint registrants with whom the Other Party was able to conclude the agreement. Therefore, the Claimant reminded that it was in the Other Party's responsibility to ensure the respect of the REACH Regulation and that it was their obligation to enable SIEF participants to register. Finally, they requested to sign the contract by 12/06/2015 or to receive a cost proposal for the data package to allow them to submit an opt-out registration. In case of failure to do so, they would inform ECHA and submit their own registration dossier.</p>	