Addressee (Claimant):

[redacted]

Sent via REACH IT to [redacted]

Copy to Existing Registrant:

[redacted]

Sent via REACH IT to [redacted]

Reference number of the dispute claim	DSH-30-3-[redacted]-2014
Decision number	DSH-30-3-D-[redacted]-2014
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 REACH REGULATION (EC) No 1907/2006

Dear Mr [redacted],

On 3 November 2014, you submitted a claim concerning the failure to reach an agreement on data sharing with [redacted] 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 Existing Registrant to provide documentary evidence regarding the negotiations. The Existing Registrant submitted the requested documentary evidence on 25 November 2014.

Based on the documentation supplied by you, ECHA has decided not to grant you permission to refer to the studies requested from the Existing Registrant for the above-mentioned substance.

The statement of reasons regarding the assessment of the data sharing dispute is set out in the Annex I. General recommendations for further data sharing negotiations are provided in Annex II.

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,

[redacted]

Christel Schilliger-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-30-3-D-[redacted]-2014

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, Article 30(3) of the REACH Regulation requires ECHA to determine whether to grant a permission to refer to the information contained in the registration dossier, *i.e.* to the corresponding studies. In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the information provided, 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.

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. In order to make every effort to reach an agreement, SIEF participants shall negotiate the sharing of data and related costs as constructively as possible to make sure that the negotiations move forward by expressing their arguments and concerns, and replying and asking relevant questions.

The Claimant initiated the negotiations with an email dated 26 July 2010. Later on, in their email dated 25 September 2012, the Claimant confirmed their intention to register the substance in 2013. They also requested details, such as how to obtain the Letter of Access (LoA), the number of expected registrants, the tentative price and method of payment for obtaining the LoA. In their response dated 27 September 2012, the Existing Registrant provided the cost calculation for different tonnage bands, a list of studies submitted for the registration of the substance and a draft joint submission agreement for the tonnage band [redacted]/a.

Following the Existing Registrant's enquiry on the registration plans, the Claimant informed the Existing Registrant with an email dated 13 November 2012 that "*our principals decided that since the volume [...] in Europe is not large enough to justify spending upwards of €* [redacted] *on registration we should restrict imports [...] and review in 2018*".

After another request on the Claimant's latest position by the Existing Registrant on 11 March 2013, the Claimant replied on the same date that they would be "*interested in obtaining the LoA details only if the price of purchase of the dossier drops dramatically from the €* [redacted] *level*".

With an email dated 15 April 2013, the Claimant requested the Existing Registrant to provide them with a cost breakdown as soon as possible in accordance with advice they had received from the UK competent authority.

With an email dated 26 April 2013, the Existing Registrant listed the items that made up the dossier fees: (i) Data Gap Analysis/Data Collection; TOX, ECO, PC; (ii) IUCLID 5 Preparation, TOX, ECO, PC; (iii) CSR creation; (iv) lump sum (administrative costs); (v) Advantage compensation according to consortium agreement. Further, they attached the cost calculation – which had been provided already on 27 September 2012 – listing the costs per participant and tonnage band: for tonnage bands [redacted]t/a, [redacted]t/a and [redacted]t/a, a price of [redacted] € ("dossier compensation") plus [redacted] € ("study compensation") was quoted. Also an overview "*on lump sum administrative costs for dossier preparation*" was provided, laying out a number of tasks and related time consumption.

With their email of 23 August 2013, the Claimant asked whether there was a recalculation of the cost of LoA as there was an additional registrant now. Further, they asked about the application of a refund mechanism. In their reply of the same day, the Existing Registrant wrote that as one of the registrations was "*for a special application*" with a tonnage band [redacted]t/a, the previously quoted costs were still valid. Further, they informed the Claimant that internal discussions on "*how to proceed with potential new joint submission partners in terms of LoA costs*" were on-going and promised to inform the Claimant "*as soon as possible*".

Pending a reply, on 13 September 2013 the Claimant reminded the Existing Registrant to inform them about any news on the LoA costs and informed that they were "*looking for registration in the bracket [redacted]pa*". The Existing Registrant replied on 3 October 2013 that for "*administrative reasons*" they would "*prefer to maintain the present LoA calculation*" and that by mid-2018 they "*will calculate all revenues and compare them with the definite cost pattern*". They further informed that they expected additional costs related to dossier updates and expressed their hope that their approach would lead to a "*fair and final costsharing option*".

On 1 April 2014, the Claimant contacted the Existing Registrant requesting "*costing information apart from the lump sum information that you [Existing Registrant] sent me [Claimant] last year [2013]*".

With their reply dated 3 April 2014, the Existing Registrant provided details on the composition of the "*external costs (costs we [Existing Registrant] have to pay to external consultants for services rendered)*", consisting of the following cost items: (i) data gap analysis / data collection, (ii) IUCLID 5 preparation, and (iii) CSR preparation.

After the receipt of the details related to the external costs on 03 April 2014, the Claimant did not continue the negotiations and lodged the data sharing dispute claim on 3 November 2014.

Based on the information provided, ECHA assessed the efforts made by the parties.

The Claimant requested the cost breakdown on 15 April 2013, which was, together with the follow-up question on 1 April 2014, an important contribution to advancing the negotiations in a constructive manner. Without this information, the negotiations cannot move forward,

and the Claimant is not in the position to decide whether the price of the LoA was calculated in a fair, transparent and non-discriminatory way.

By providing the cost breakdowns on 27 September 2012 (on the Existing Registrant's initiative), 26 April 2013 and 03 April 2014, the Existing Registrant addressed the requests of the Claimant, and it was an essential part of making every effort and of increasing transparency by the Existing Registrant.

In spite of the information provided by the Existing Registrant in their emails dated 27 September 2012, 26 April 2013 and 03 April 2014, ECHA notes that the Claimant never challenged the position of the Existing Registrant and more particularly the breakdown of the costs. Rather, the Claimant stated that they "*would be interested in obtaining the LoA details only if the price [...] drops dramatically*". Instead of raising any argument challenging the cost breakdown and the listed items in more detail, the Claimant opted to discontinue the negotiations and, seven months after the last communication with the Existing Registrant, submitted a data sharing dispute claim to ECHA.

However, ECHA expects that if the Claimant still disagreed with the conditions for sharing the data, they should have continued the negotiations with the Existing Registrant before submitting a data sharing dispute.

Therefore, if the Claimant still disagreed with the conditions for sharing the data, they should have provided the Existing Registrant with relevant arguments, precise questions or alternative proposals, placing them in a position to justify or clarify their claim and allowing the negotiations to continue until an agreement is finally reached. By not providing such arguments requesting the Existing Registrant to justify their cost proposals, the Claimant did not contribute effectively to the data sharing negotiations.

The above demonstrates that not all efforts had been exhausted by the Claimant before submitting their data sharing dispute claim to ECHA. Based on the communication between the parties, ECHA concludes that the Claimant has not made every effort to reach an agreement with the Existing Registrant on the sharing of costs of the data in a fair, transparent and non-discriminatory way, as required by Article 30(1) of the REACH Regulation, and ECHA therefore requests the parties to continue their negotiations and to make every effort to reach an agreement.

Annex II to decision DSH-30-3-D-[redacted]2014

GENERAL RECOMMENDATIONS FOR FURTHER DATA SHARING NEGOTIATIONS

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

- Both parties still share the obligation to make every effort to find an agreement on data sharing after this decision, and are encouraged to take the present decision into account in their further negotiations;

- Making every effort in reaching an agreement requires both the potential registrant and the existing registrant 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;

- Based on the REACH requirement of non-discriminatory and fair data sharing, *inter alia*, registrants are required to pay only for their actual needs. 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 of the requested compensation;

- 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 other party, cannot be taken into consideration in the assessment by ECHA (as confirmed by the recent decision of ECHA's Board of Appeal of 17 December 2014 in the appeal case A-017-2013, in paragraphs 99-100);

- ECHA would like to remind both parties that the data sharing dispute assessment relies on the information provided by both parties. Therefore, it is essential to provide a full set of documentation describing all efforts made in the negotiations;

- If the future data sharing negotiations would fail again, the Claimant 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 reminds you that following Article 16 of Regulation (EC) No 1049/2001, the documents attached are subject to copyright protection."