[redacted]

Addressee (Claimant):

[redacted]

Sent via REACH IT to [redacted]

Copy to Other Party:

[redacted]

Sent via REACH IT to [redacted]

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 Ms [redacted],

On 28 April 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') represented during the data sharing negotiations by the [redacted] (hereinafter referred to as 'the Consortium'), 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 requested documentary evidence on 22 May 2015.

Based on the documentation supplied by both parties, ECHA has decided not to grant you, as the Claimant, permission to refer to the studies requested from the Other Party for the above-mentioned substance.

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

[redacted]

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 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

[redacted]

Annex I to decision DSH-30-3-D[redacted]-2015

STATEMENT OF REASONS REGARDING THE ASSESSMENT OF THE DATA SHARING DISPUTE

Pursuant to Article 30(1) of the REACH Regulation, *"Within one month of the request, the owner of the study shall provide proof of its cost to the* [SIEF] *participant(s) requesting it. The 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 already submitted by another registrant, 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.

Factual background

The Claimant initiated the negotiations with an email dated 7 August 2014 expressing its interest in data and cost sharing in relation to three substances. Responding to the Claimant's request, the Consortium explained that the substances have been registered by its members and that a Letter of Access (LoA) to the existing joint submissions can be purchased by those wishing to become co-registrants.[1] In reply, the Claimant confirmed its interest in buying a LoA for those substances.[2] The final cost of the LoA was subsequently provided by the Consortium.[3] The substance subject to the data sharing dispute at hand was not yet among these three substances.

After receiving the information on the final cost for the LoA, the Claimant requested to be provided with the list of studies used for the registration of the three substances and information about the *"cost of each study used to build the dossier and how the cost of the LoA has been calculated"*.[4] The Consortium explained that the registrations submitted by its members, including for the three substances of interest, have been based on the grouping of substances *"according to structural similarity in order to benefit from the development of category approach to support read-across from data to similar substances where appropriate"*.[5] It was pointed out that due to the chosen data sharing model based on the category approach while *"each dossier will refer specifically to individual studies"*, *"there is not direct link to the costs of individual studies for each dossier"* and the costs of all data are shared between all co-registrants within the respective group and their respective tonnage band. The cost breakdown of the LoA was also provided while for the requested list of studies, the Claimant was directed to ECHA's dissemination website with the argument

[1] Email dated 7 August 2014.
[2] Email dated 22 August 2014.
[3] Emails dated 26 August 2014.
[4] Email dated 26 August 2014.
[5] Email dated 27 August 2014.

that the information concerning studies used in the dossiers *"is publicly available on the ECHA dissemination website and is not information that I* [the Consortium] *have in prepared form for potential co-registrants"* and that *"to construct a list of studies for the 3 dossiers of interest will take several hours and will not tell you any more than you can see on the ECHA website"*.

The Claimant replied[6] that *"while in ECHA dissemination website some data of the studies can be kept confidential [...] the same is not possible during data sharing process with other co-registrants"*. Therefore, the Claimant requested the Consortium to *"identify exactly each study/studies used for each endpoint and to explicit the requested cost for each study"* to allow it to *"correctly exercise our [Claimant's] right as co-registrant or, eventually, opting out registrant"*.

Nevertheless, a day later, the Consortium provided a list of the studies used to cover each endpoint for the registration of the three substances.[7] The requested study by study breakdown of costs did not appear in that list. The Consortium explained that the names of the study owners were not disclosed to *"protect the confidential business information of my clients"* and that a study by study breakdown of costs allocated to each dossier has not been provided *"for the simple reason that this is not how we calculated the LoA costs"*

With its email dated 2 September 2014, the Claimant extended the scope of its data and cost sharing request to another six substances, including the substance subject to the dispute at hand. In response, the Consortium confirmed that the information provided earlier on the LoA and the chosen data and cost sharing model was also relevant to those additional six substances.[8] Regarding the list of studies used for the registration of those six substances, the Consortium directed the Claimant to ECHA's dissemination website. The Claimant replied that the information appearing on ECHA's dissemination website was not sufficient for registration purposes and repeated its request for the list of studies for the additional six substances as well as for the costs of the studies used in the registration of all nine substances under negotiation.[9] It also pointed out that at this stage it is *"not interested in any LOA to dossiers as a whole"* but *"in single studies contained in each dossier"*.

In its reply, the Consortium explained that *"Individual studies are not owned by the Consortium and I have no instruction from our members to negotiate on their behalf for access to individual studies. All the studies referenced in the* [Consortium's] *dossiers remain the property of the company who commissioned them and any request for access to the studies and any discussion regarding cost compensation must be directed to the study owner. On previous occasions I have received specific requests for individual named studies [...] and I have passed these to the study owners to take up the contact directly"*.[10] It also stated that *"In the present case, your* [Claimant's] *request is large and general and without the focus on specific endpoints and will take a significant investment in my time. [...] I will need to consult all of the data holders and obtain their express permission to give you what*

[6] Email dated 28 August 2014.
[7] Email dated 29 August 2014.
[8] Email dated 2 September 2014.
[9] Email dated 4 September 2014.
[10] Email dated 5 September 2014.

you really require ie, the identity and contact details of the owner of each study." The Claimant was therefore requested to identify the specific studies it would wish to negotiate access to with their respective data owners.

The Claimant responded that it was *"interested in a joint submission"* with the Consortium members and not in receiving the identity and contact details of the data owners.[11] The Claimant repeated its request for the *"identification of each study and amount requested for sharing each study"*. The Consortium then provided[12] a list of the studies referred to in the registration dossiers of all nine substances as well as the final cost of the LoA per tonnage band and stated again its willingness to put the Claimant into contact with the respective data owners.[13] In its reply, the Claimant stated that *"the cost of each study for the eventual co-registrant has not been explicated"*[14] and reiterated its request for the *"cost of the LoA to each study contained in the dossiers of our concern, in the context of a potential co-registration, where we reserve the right to opt-out certain specific studies"* pointing out that this is the reason *"why our interlocutor is supposed to be the* [Consortium], *not each single data owner"*.[15]

The Consortium explained[16] that no prices were assigned to the individual studies as the cost calculation had not been set-up with opting out in mind, but that it had however been possible to accommodate earlier requests for opt-outs regarding individual studies.

The Consortium invited the Claimant to explain *"which parts of the joint submission dossier you may wish to opt out of"* indicating that *"if different data is inserted in an opt-out dossier then the existing justifications and conclusions may no longer be valid"*.[17] It pointed out that a discussion between the Claimant and the respective *"study owners [..] might be needed to submit an opt-out dossier"*. It also explained that the Consortium *"acts as a focal point [..] for initial communication between potential co-registrants and Lead Registrants"*, that the *"SIEF agreements remain the responsibility of individual Lead Registrants"* while, in case a company requires access to individual studies, the Consortium or the Lead Registrant is directing *"the enquirer to the data-owner who is able to arrange access to the study against appropriate cost compensation"*.[18] The Consortium also provided a table which included for all nine substances the cost breakdown per endpoint within the category model adopted by the existing registrants, and the total costs of the data used in the registration of the nine substances for each tonnage band, before and after repartition among the co-registrants.

In response, the Claimant expressed its dissatisfaction on the information it had received so far, arguing that the Consortium did *"not send at all what repeatedly and clearly requested"* and that *"the cost of each individual study for the potential co-registrant appears*

[11] Email dated 8 September 2014.
[12] Email dated 24 September 2014.
[13] Email dated 6 October 2014.
[14] Email dated 3 October 2014.
[15] Email dated 7 October 2014.
[16] Email dated 9 October 2014.
[17] Email dated 10 October 2014.
[18] Email dated 27 October 2014.

nowhere".[19] It indicated that, if it would not have received the requested information within 15 days, it would submit a dispute claim to ECHA. The Consortium took note of the lack of agreement between the parties and informed that the offer for data and cost sharing "*based on the same terms as all the other co-registrants of course remains open*".[20]

Between 17 November 2014 and 7 April 2015 there had been no further communication between the parties. On 7 April 2015, the Claimant informed the Consortium that it would submit a dispute claim to ECHA arguing that the Consortium "*and the Lead Registrants involved requested the payment of a generic fee for the LoAs to joint registration dossiers of the substances [..] without providing information on the cost requested [..] for access to each individual study*". The Consortium replied that the Lead Registrants had "*considered again your* [the Claimant's] *request for individual costings per substance; however since the costing methodology adopted by* [the Consortium] *has been in use since 2010 and [...] has been accepted by over 120 co-registrants; we feel that it would now be unfair on the existing co-registrants to make any special calculation*".[21]

The dispute claim was submitted to ECHA on 28 April 2015.

Assessment

As referred to further above, the parties in data sharing negotiations have the obligation to make every effort to reach an agreement on the sharing of studies and their costs in a fair, transparent and non-discriminatory way. In order to make every effort to reach an agreement, the parties 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. Notably, they should take into account the information they have received from the other party and use it effectively in order to find a common understanding on which the data and cost sharing agreement can ultimately be based upon.

In the beginning of the negotiations, the Claimant sought by the Consortium the list of studies used in the registration of the disputed substance along with their respective costs. ECHA notes that this information enables a potential registrant to reach a common understanding with the existing registrant(s) on the sharing of data and their costs. It also allows a potential registrant to determine its own registration strategy, including whether to opt-out from the jointly submitted information.

ECHA also remarks that the Consortium could have been more proactive in facilitating the contacts between the Claimant and the respective data owners. The Consortium indicated that the provision of the data owners' contact details would take it a significant investment in time and invited the Claimant to identify the studies it would be interested in negotiating access to with their respective data owners. ECHA notes that a potential registrant is free to negotiate access to all or some of the studies and it can ask for all studies available within a

[19] Email dated 6 November 2014.
[20] Email dated 17 November 2014.
[21] Email dated 16 April 2015.

SIEF.[22] An increased workload for the Consortium cannot result in raising obstacles to the effective exercise of the Claimant's right to obtain the proof of cost of the studies used in the registration of the disputed substance. While it is in the existing registrants' discretion to agree on a data and cost sharing model for the registration of a substance, such a choice should not obstruct the legitimate interests of a potential registrant, including its contacts with the respective data owners. The more complex the chosen data and cost sharing model is the more efforts are required by the existing registrants to explain it and provide necessary clarifications to a potential co-registrant.

The Consortium initially directed the Claimant only to ECHA's dissemination website for the requested list of studies. However, the Claimant rightly indicated, that this does not contain sufficient information for registration purposes. Thereafter, the Consortium provided information on the studies used for the registration of the disputed substance. With regard to the individual costs of each study used in the registration of the disputed substance, the Consortium explained that due to the chosen data and cost sharing model of the category approach the costs of all data are shared between all co-registrants in the category and thus there is no direct link between the cost of each study and each individual dossier. The Consortium explained that it was not mandated to negotiate access to individual studies and discuss their respective costs, but it was only empowered to carry out the initial communications with regards to access to the existing joint submissions which have been built based on the data and cost sharing model of the category approach. In addition, the Consortium demonstrated its willingness to explain to the Claimant the details of the chosen data and cost sharing model of the category approach over the phone. ECHA remarks that it was the existing registrants' decision not to mandate the Consortium to negotiate access to individual studies and to provide the proof of costs in accordance with Article 30(1) of REACH. Nevertheless, such a decision may not in practice limit or obstruct a potential registrant's right to obtain the proof of the study costs.

Despite its initial positive efforts, i.e. requesting the list of studies and their costs, the Claimant subsequently failed to consider and use the information provided by the Other Party which might have allowed the negotiations to progress. This is particularly true with regard to a registration dossier jointly submitted in the context of a grouping of several substances. Indeed, in such case, the essence of the dossiers submitted for each substance covered by the category is to provide supporting evidence of the category, including theoretical considerations and results from studies performed on some of the substances of the category. If a registrant wishes to opt out from the category approach, he should specify from the bulk of studies supporting the category, which particular study he intends to refer to separately for his specific substance.

Although the Consortium clearly explained that it is not mandated to negotiate access to individual studies, the Claimant insisted throughout the negotiations on receiving the costs of each study used in the category by the Consortium. The Claimant refused to get in contact, with the help of the Consortium, with the respective data owners. Requesting the contact details of the data owners and entering into negotiations with the latter could however have enabled the Claimant to receive the proof of the study costs and thus

[22] See also the decision of the Board of Appeal in the appeal case Vanadium vs ECHA, A-017-2013, at para.78.

effectively exercise its right under Article 30(1) of REACH. It would have also allowed the Claimant to conclude whether a self-built dossier would have been more advantageous for it than the chosen model of the category approach, and thus decide whether to avail itself of its right for opting out from the jointly submitted information. Without having previously explored this option and by insisting on addressing its request to the Consortium who was not entitled to negotiate access to individual studies and discuss their costs, the Claimant failed to enable the negotiations to move forward. Thus, the Claimant did not make every effort to find an agreement on sharing the data and their costs based on the chosen data and cost sharing model of the category approach nor did it make every effort to receive the proof of costs of individual studies from their respective data owners.

In its assessment, ECHA needed to conclude if the Claimant has complied with its obligation to make every effort to reach an agreement on the sharing of data and their costs in a fair, transparent and non-discriminatory way as required by Article 30(1) of the REACH Regulation before it submitted the data sharing dispute claim to ECHA. Regardless of the efforts made by the Other Party, ECHA cannot grant a permission to refer to the requested data if the Claimant has not exhausted every effort.

The above demonstrates that the Claimant did not exhaust every effort to reach an agreement with the Other Party. Consequently, ECHA cannot grant the Claimant a permission to refer to the requested information.

However, ECHA notes that also the Other Party could have made more efforts as explained in the above assessment.

Both parties are still obliged to comply with their data sharing obligation to make every effort to reach an agreement after this decision and are thus strongly encouraged to continue their negotiations.

Annex II to decision DSH-30-3-D[redacted]-2015

GENERAL RECOMMENDATIONS FOR FURTHER DATA SHARING NEGOTIATIONS

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

- Despite of the current decision not granting the Claimant permission to refer to the requested information, both parties still share the obligation to make every effort to find an agreement on data sharing after this decision, and are strongly encouraged to take the present decision into account in their further 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 points out that it is important to use correct and consistent terminology in the communication between the parties involved to avoid any misunderstandings;

- It is suggested that the parties involved define their roles and mandates in the negotiations as early as possible. If a party informs the other that it is not empowered to answer a specific request, it should facilitate contact to the correct person. The other party should then follow up with that person.

- ECHA reminds the parties that they are obligated to form part of the same joint submission. The data and cost sharing model cannot obstruct the right to opt-out from the jointly submitted information, nor can it obstruct the right to become a member of the joint registration.

- 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 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.