[redacted]

Helsinki, 30 January 2018

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

Represented by

[redacted]

Decision number: [redacted]
Dispute reference number:
Name of the substance:
EC number of the substance:

DECISION ON A DISPUTE

a. Decision

Based on Article 30(3) of Regulation (EC) No 1907/2006 ('REACH Regulation')[1],

ECHA does not grant you permission to refer to the information you requested from the Existing Registrant, [redacted], represented by [redacted], of the above-mentioned substance.

The reasons for this decision are set out in Annex I. Advice and further observations are provided in Annex II.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p.1, as last amended.

[redacted]

b. Procedural history

On 29 October 2017, you (the 'Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with [redacted], represented by [redacted] (the 'Other Party'), as well as the related documentary evidence, to ECHA. To ensure that both parties would be heard and that ECHA could 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 24 November 2017.

c. Appeal

This decision can be appealed to the Board of Appeal of ECHA within 3 months of its notification. An appeal, together with the grounds thereof, should be submitted to the Board of Appeal of ECHA in writing. An appeal has a suspensive effect and is subject to a fee. Further details are available here: http://echa.europa.eu/web/guest/regulations/appeals.

Yours sincerely,

Christel Schilliger-Musset[2]

Director of Registration

[2] 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.

[redacted]

Annex I: REASONS FOR 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 that 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 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 of 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

The Claimant initiated the negotiations on 17 December 2015, requesting from the Other Party information about the terms and conditions for a letter of access ('LoA') for the tonnage band [redacted] they intended to register.[3] In turn, on 27 April 2016, the Other Party provided a link to their website, stating it was updated according to the 2018 tonnages.[4]

On 1 August 2017, the Claimant confirmed their interest in the full registration for [redacted] and requested confirmation as to whether the earlier provided information was up-to-date.[5] The Other Party replied affirmatively on the same day.[6]

On 11 August 2017, the Claimant raised concerns about some provisions of the LoA agreement, in particular related to the [redacted] obligations based on the agreement and the provision of a cost itemisation[7], to which the Other Party responded on 14 August 2017[8].

On 5 September 2017, the Claimant inquired about the current number of registrants and about the LoA cost for [redacted] dossier based on this figure.[9] On the same day, the Other Party provided the current LoA cost for the dossier in [redacted] and explained that the Claimant '*will be asked to pay an LoA top up fee […] later this year*'. The Other Party explained that due to the low number of registrants for the substance in question, they '*decided to merge the costs for [the substance in question] with the costs for 2 other substances'* as *'they all share properties and data can be used for all of them'*. The Other Party indicated that they enclosed an attachment[10] explaining further their calculations and the charging of '*a top up fee'*.[11]

On 6 September 2017, the Claimant challenged the amount of [redacted] running costs and asked whether a reduction of these costs had been considered. They also raised concerns about some provisions of the LoA agreement and inquired about '*the possibility of changing*

[3] The Claimant, 17 December 2015
[4] The Other Party, 27 April 2016
[5] The Claimant, 1 August 2017
[6] The Other Party, 1 August 2017
[7] The Claimant, 11 August 2017
[8] The Other Party, 14 August 2017
[9] The Claimant, 5 September 2017
[10] The Other Party provided this attachment as part of their evidence in the dispute, without explicit information about which email it was attached to. Based on the email exchanges among the parties, ECHA understands that it was provided with this email of the Other Party of 5 September 2017.
[11] The Other Party, 5 September 2017

[redacted]

in agreement'. The Claimant further requested the list of studies for the merged group of substances, pointing out that the study cost for their group of substances was the highest.[12]

In their reply of 13 September 2017, the Other Party explained that the [redacted] running costs were divided into 'management costs', 'general costs' and 'operating costs' and gave some examples of what was included under each cost item. The Other Party confirmed that the study cost for the Claimant's group of substances was the highest as there were 6 substances and the group had shared costs for expensive [redacted] studies. They indicated that they attached the list of studies for the substance[13], based on a read-across approach. Regarding the possibility of changes in the agreement, the Other Party inquired which changes the Claimant wanted to see in the agreement.[14]

On 18 September 2017, the Claimant still considered that the [redacted] *costs [were] unfounded*', referring to the costs of similar [redacted] They also asked for the costs of the studies included in the Other Party's calculation. Regarding the agreement, the Claimant suggested (i) to remove a clause that envisaged a penalty charge in case of registration of a substance for which the company was not granted a LoA; and (ii) to change the jurisdiction, from [redacted] courts to the [redacted] Institution of Arbitration [redacted].[15]

In their reply of 22 September 2017, the Other Party claimed that new ways and ideas were examined to help reduce the [redacted] running costs. The Other Party refused to remove the penalty clause and proposed instead to amend it. They considered this clause as justified to avoid SIEF members registering without paying for the LoA. With regard to the change of jurisdiction, the Other Party refused the Claimant's proposal as it could cause '*never ending*' changes for each SIEF member.[16]

On 19 October 2017, the Claimant disagreed with the refusal of the Other Party to remove the penalty clause from the agreement, stating that '*it is obvious that everyone has to pay for data access*' and referring to their agreements with [redacted]. The Claimant agreed with the Other Party's arguments regarding the change of jurisdiction. However, regarding the costs, they reiterated that they were '*unfounded*', and explained that they found the proportions between the study costs and the [redacted] costs *'not proper*'. Since they were *'afraid that [their] further discussion will not lead to a common position on this matter*', the Claimant indicated the possibility to submit a dispute to ECHA.[17]

The Other Party replied on the same date, first asking whether there were '*any issues to clarify on the study cost'* and '*any concerns with [the substances] considered under the read across umbrella*'. They indicated that they attached a breakdown of the study costs[18]. Second, regarding the [redacted] running costs, the Other Party explained that some items and studies were beneficial for all the substances, e.g. the studies necessary for the derivation of the [redacted] This is why the costs were divided equally among all substances. The Other Party justified a calculation of the costs based on all dossiers rather than for each one, because the time spent on a dossier is reduced with the gain of

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[12] The Claimant, 6 September 2017

[13] Both parties provided as part of their evidence in the dispute an excel table providing a cost per endpoint and the substance on which the study was conducted. Based on the email exchanges among the parties, ECHA understands that this excel table was exchanged in that email of the Other Party of 19 October 2017.

[14] The Other Party, 13 September 2017

[15] The Claimant, 18 September 2017

[16] The Other Party, 22 September 2017

[17] The Claimant, 19 October 2017

[18] Both parties provided as part of their evidence in the dispute an excel table providing a cost per endpoint and the substance on which the study was conducted. Based on the email exchanges among the parties, ECHA understands that this excel table was exchanged in that email of the Other Party of 19 October 2017.

[redacted]

experience. Finally, regarding the submission of a dispute to ECHA, the Other Party asked the Claimant which further information they would like to discuss, so the Other Party could know whether they had explained their '*entire rationale'*.[19]

On 20 October 2017, the Claimant raised some questions on the methodology used to derive [redacted] and the connection of these costs with their substance.[20] The Other Party replied on the same day to justify the use of this methodology and they indicated that this cost item was divided equally among all substances because it benefits all substances.[21]

In their last reply of 25 October 2017, the Claimant said that they had analysed all the information provided, and they raised concerns on some of the studies included in the study breakdown provided by the Other Party. In particular, they claimed that these studies (i) were not included in the dossier for the substance in question on ECHA's website; and (ii) were not required for the Claimant's tonnage band [redacted].

Regarding the costs calculation and their allocation, the Claimant agreed with the use of an '*average value*' for the cost of preparing the dossiers in IUCLID. However, they considered that '*costs connected strictly with dossier preparing should be separated from administrative costs*' and that these costs '*should be varied depending on tonnage band'.* They challenged the [redacted] approach of grouping substances and '*divid[ing] all cost by a number of substances and a number of participants*'. They indicated that an alternative cost-sharing model would be *'to divide the study cost by a number of registrants which indeed used the study'.* Regarding the [redacted] running costs, the Claimant claimed that they were disproportionate and requested more detailed explanations. They further claimed that the model for sharing these [redacted] costs was not clear to them and proposed an alternative sharing model.

Finally, the Claimant disagreed again with the clause foreseeing a penalty charge and challenged the justification of the Other Party regarding the methodology used for [redacted] calculation.[22]

The Claimant submitted the dispute on 29 October 2017.

Assessment

According to Article 30(1) REACH and as reinforced by the Commission Implementing Regulation (EU) 2016/9[23] (hereinafter the 'Commission Implementing Regulation'), the parties need to make every effort to reach a fair, transparent and non-discriminatory agreement on the sharing of data and the joint submission of information. Making every effort means to negotiate in a clear and constructive manner to enable the parties to find a mutual understanding on the data that needs to be shared and on the terms of sharing this data in a fair, transparent and non-discriminatory manner. This means that the parties need to provide answers to the questions that they receive from the other party and consider the replies they receive in turn. Further, in order to find an agreement, the parties need to challenge the points on which they disagree with clear explanations and give the other party the opportunity to react on those. Making every effort also means that the parties must continue their efforts to reach an agreement and only use the dispute mechanism under REACH as a measure of

[19] The Other Party, 19 October 2017

[20] The Claimant, 20 October 2017

[21] The Other Party, 20 October 2017

[22] The Claimant, 25 October 2017

[23] Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

last resort, when all other options have been exhausted.

From the outset, the Claimant asked for an itemisation of the study costs for their substance and requested further clarifications on the calculations, in particular regarding the [redacted] running costs. In the negotiations, the Other Party provided a cost overview and some itemisation of the study costs. They provided further explanations on their cost-sharing model, in particular on the use of read-across, on the items included in the [redacted] running costs and on the advantage of grouping the administrative costs. Furthermore, the Other Party did not refuse the idea of modifying some provisions of the agreement and pro-actively asked the Claimant whether they needed some further clarification regarding the study costs and grouping of substances '*under the read across umbrella*'[24]. This behaviour showed that the Other Party took some steps in the negotiations in order to get closer to the finding of an agreement with the Claimant.

During the negotiations, both parties communicated in a timely manner and managed to reach common ground on some issues, such as the competent jurisdiction for the agreement or the use by the [redacted] of an average value of the cost of preparing the dossiers in IUCLID. This shows that both parties made efforts on some items in order to facilitate the finding of an agreement. However, some points of disagreement remained, e.g. on the clause regarding a penalty charge or on the method used for the derivation of [redacted]. Further, some concerns raised by the Claimant, e.g. on the fairness of the sharing of the [redacted] costs among the substances and the registrants, were not fully clarified by the Other Party in the negotiations.

In their last email of 25 October 2017, the Claimant raised new substantial issues, in particular regarding the relevance of some studies for their tonnage band and the absence of inclusion of these studies in the disseminated dossier on ECHA's website. Consequently, they challenged the fact that they would be required to pay for these studies. They also raised further questions on the Other Party's cost-sharing model. However, the Claimant filed a data-sharing dispute with ECHA only four days after sending these substantial questions to the Other Party. Moreover, they had not indicated in this last email a specific urgency that would have required a reply by the Other Party within four days. Thus, by filing the dispute without giving the Other Party sufficient time to reply to newly raised issues, the Claimant did not give them the opportunity to reply.

As also indicated in the ECHA's guidance on data sharing, a data-sharing dispute 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'*.

ECHA observes that the negotiations were still in full progress when the Claimant launched the dispute. Both parties were actively engaged, and the Claimant could have continued their efforts to come to an agreement. Instead, by filing the data-sharing dispute only few days after raising new points of discussion and of disagreement, the Claimant did not give the Other Party time to react to their arguments and to take steps to find a solution to these issues. Moreover, in view of the prompt replies received from the Other Party throughout the negotiations, the Claimant did not have a reason to fear that they would not receive a prompt reply from the Other Party. Therefore, the submission of the data-sharing dispute was premature. By submitting a dispute before all efforts were exhausted, the Claimant failed to make every effort.

[24] The Other Party, 19 October 2017

[redacted]

Conclusion

Based on the above, ECHA concludes that by not exhausting all efforts, the Claimant did not make every effort to reach an agreement on data sharing and access to the joint submission in a fair, transparent and non-discriminatory way.

Consequently, ECHA has decided not to grant the Claimant the permission to refer to the information they requested from the Other Party.

[redacted]

Annex II: ADVICE AND FURTHER OBSERVATIONS

ECHA stresses that both parties still share the common data-sharing and joint submission 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. ECHA notes that some items in the present negotiations have not been clarified and the outcome of the present decision mainly results from the lack of opportunity given to the Other Party to reply to the issues raised by the Claimant. In order to make every effort in the future negotiations, the Other Party should provide answers on these points. ECHA encourages both parties to take into consideration the remarks given below to facilitate the negotiations and to reach an agreement on data sharing:

- Parties in data-sharing negotiations should clearly explain their position and the questions they have, challenge the points they disagree with and assess the justification given in turn. It is also crucial that existing registrants enable potential registrants to understand their cost-sharing mechanism, in order to facilitate further discussions towards an agreement (Article 2 of the Commission Implementing Regulation). In this regard, ECHA understands, e.g., that the Claimant found unclear the distinction between the different administrative costs and the model used for the sharing and allocation of costs among substances and among registrants. This may need to be clarified by the Other Party in order to allow the Claimant to fully understand the cost-sharing model and be in a position to assess it.

- Moreover, as stated by the REACH Regulation and reaffirmed by the Commission Implementing Regulation, registrants are only required to share the costs of information that they need to fulfil their registration requirements (see Article 30(1) of REACH and Article 4(1) of the Commission Implementing Regulation). This means that registrants need to share the costs of data that relates to their information requirements, considering the tonnage band they intend to register. This applies to both study and administrative costs (Article 4(1) of the Commission Implementing Regulation). In this regard, ECHA understands that the Claimant challenged the inclusion in the study costs of some studies relevant for higher tonnage bands. This issue may need to be explained and further justified by the Other Party in future negotiations. ECHA understands that the Claimant also raised concerns on the '[redacted] running costs'. The relevance of those costs for the Claimant could also be discussed and clarified by the Other Party in future negotiations.

- Further, parties in data-sharing negotiations should consider different options to unblock and advance the negotiations, including the possibility to adapt their stance in order to get closer to an agreement based on transparency, fairness and non-discrimination. In this sense, the fact that an agreement was reached in the past among the [redacted] members does not bind future registrants. Existing registrants must demonstrate how the cost-sharing model and the items it includes are of relevance to the new registrants and are fair, transparent and non-discriminatory towards them. A model that was fair, transparent and non-discriminatory towards existing registrants may not fulfil these requirements towards new registrants. This model may then require adaptation.

- If future negotiations fail, the Claimant is free to submit another claim, covering all the efforts made in the negotiations. However, 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.