[redacted]

Helsinki, 9 May 2018

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

Represented by

[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 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. The list of studies ECHA grants you permission to refer along with copies of (robust) study summaries can be found in Annex II and III, respectively. Instructions on how to submit your registration dossier are provided in

[redacted]

Annex IV.

b) Procedural history

On 16 February 2018, 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 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 01 March 2018.

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.

The present decision will be published in an anonymised version on ECHA's website[1].

Yours sincerely,

Christel Schilliger-Musset[2]

Director of Registration

[1] Available at https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach.

[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 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 19 May 2016, the Claimant informed the Other Party of their intention to purchase the Letter of Access (hereinafter 'LoA') for REACH registration and asked for an '*an indicative price for the LoA based on the data package costs, admin fees and the likely number of registrants*'.[3] The following day, the Other Party replied to the Claimant that they '*[were] in the middle of* [redacted] *update*' and therefore they needed more time to calculate the approximate cost for the LoA, and confirming that there were other potential registrants for the substance.[4]

On 22 July 2016, the Other Party provided the estimated LoA costs for [redacted] and [redacted] tonnage bands based on a preliminary estimate of the number of potential registrants per tonnage band.[5] On the same day, the Claimant acknowledged receipt of the email and wrote that they would inform the Other Party of their decision later.[6]

On 19 October 2016, the Claimant informed about their interest in proceeding with their registration and requested '*the SIEF agreement etc*'.[7] On 21 October, the Other Party inquired about the tonnage band of the Claimant[8], the latter provided the answer the same day, their tonnage band being [redacted] tpa[9]. On 24 October 2016, the Other Party contacted the Claimant and informed that the LoA costs had changed as a result of a substance evaluation where the Other Party had conducted new studies and updated the registration dossier so that '*now we have all these costs included into the LoA calculation*'. Further, the Other Party informed that other companies expressed their interest in registration and that would reduce the current LoA cost, and provided the Claimant with the SIEF agreement.[10] The same day the Claimant requested further details on the cost breakdown, namely the cost of each endpoint study, more detail on the data entry charges and more detail on the administrative charges.[11]

Following a reminder by the Claimant of 10 November 2016[12], the Other Party provided the list of studies with allocation to the REACH Annexes with costs and '*a detailed cost allocation of the dossier compilation costs*' on 15 November 2016[13]. The Claimant replied on 30 November 2016 and noted that [redacted] tests [redacted] belonged to Annex [redacted] and were

[3] The Claimant; 19 May 2016.
[4] The Other Party; 20 May 2016.
[5] The Other Party; 22 July 2016.
[6] The Claimant; 22 July 2016.
[7] The Claimant; 19 October 2016.
[8] The Other Party; 21 October 2016.
[9] The Claimant; 21 October 2016.
[10] The Other Party; 24 October 2016.
[11] The Claimant; 24 October 2016.
[12] The Claimant; 10 November 2016.
[13] The Other Party; 15 November 2016.

not required for their registration in [redacted] tonnage band, therefore they asked the Other Party to subtract *'Annex [redacted] data costs and the associated dossier costs'* from the LoA cost.[14] On 1 December 2016, the Other Party explained that the tests at question had been carried out as a result of the substance evaluation, thus *'costs will be shared by all registrants equally and are not allocated to a volume band'* and that such *'post-registration duties may not be linked to the information requirements of the individual registrant'*. The Other Party stated that *'this is common use within SIEF leadership teams and consortia'* and the cost for a LoA in the [redacted] tpa could not be reduced.[15]

On 5 December 2016, the Claimant informed that they *'simply want[…] to carry out the first step of registration and not be charged for tests that are not required for a registration in the [redacted] band'*. The Claimant argued that substance evaluation costs *'should not be linked to a company's ability to purchase a Letter of Access to enable it to jointly register a substance'*. They wrote that according to the proposed *'costing structure'* the Other Party would charge the Claimant the same amount for the substance evaluation as a company in the [redacted] band, which was *'clearly not fair, transparent and non-discriminatory'*. The Claimant requested to be provided with a LoA that *'covers purely [their] fair proportion of the costs required for Registration'*.[16]

The Other Party replied on the following day that the current cost sharing model would not be altered because fulfilling the request after substance evaluation was a benefit for all registrants, *'substance evaluation [was] decoupled from the standard data requirement'* and costs related to substance evaluation are separated from other costs, quoting the Guidance on Data Sharing, point 5.5.5.2. They stated that the current cost-sharing model had been adapted by many consortia, as well as agreed between the Lead Registrant (LR) and co-registrants. On this basis the Other Party reiterated that the *'LR is not going to change the current cost sharing model'*.[17]

On 21 December 2016, the Claimant wrote that if the tests from Annex [redacted] had been carried by the lead registrant for their registration in [redacted] tpa, *'then the data requirement would not have needed to be filled as the result of a Substance Evaluation decision'*. They considered it to be unfair and *'as barrier to registration'* that a potential registrant in a lower tonnage band has to share the same cost for an Annex [redacted] test as a registrant in a higher tonnage band. They inquired whether the Other Party could let them join the joint submission by paying only their share for the [redacted] data and the *'discussion of compensation for the Annex [redacted] Substance Evaluation test would then be deferred to a later time'*.[18]

In their reply of 5 January 2017, the Other Party explained that there was difference *'between dossier requirements and additional requirements after substance evaluation'*, and ECHA conducted substance evaluation and requested additional data which might be Annex specific, but cannot be counted as part of the dossier requirements. They quoted Article 4(2) of the Commission Implementing Regulation stating it *'does clearly except the substance evaluation'* and the equal split of data and costs to all registrants after substance evaluation *'is thus compliant'*. They noted that it is *'the policy of [the Other Party] that dossier evaluation costs will be split between all registrants, independent of the volume band'*, and that *'all current registrants have paid their equal share to the substance evaluation data costs'* and on this basis *'there is no possibility to go back on this decision and lower the LoA fee for any company'*.[19]

After an interval of ten months, on 6 November 2017, the Claimant contacted the Other Party

[14] The Claimant; 30 November 2016.
[15] The Other Party; 1 December 2016
[16] The Claimant; 5 December 2016.
[17] The Other Party; 6 December 2016.
[18] The Claimant; 21 December 2016.
[19] The Other Party; 5 January 2017.

[redacted]

again, inquiring whether any changes had taken place regarding the cost of the LoA for the [redacted] tonnage band.[20] On 7 November 2017, the Other Party informed about a LoA cost recalculation due to a dossier update and a new registrant joining the joint submission, and communicated the updated LoA cost.[21] On the same day, the Claimant requested a new detailed cost breakdown for the price of a LoA for the [redacted] tonnage band[22], which was provided to them on the same day[23].

In their email of 7 December 2017, the Claimant requested the latest SIEF agreement and noted that, based on the new calculations, they would still be charged for [redacted] tests from the higher tonnage band requirements and in their opinion, the suggested cost-sharing model is unfair. They pointed out that the Other Party previously had made a reference to the Guidance on data sharing point 5.5.5.2 reading *'According to the Implementing Regulation, all registrants, including future registrants, have to agree on a cost sharing mechanism that addresses potential costs following a substance evaluation decision. The reason is that data generated as a consequence of a substance evaluation decision may be relevant for all registrants of a particular substance. The sharing of costs shall be separated from other costs (see Article 4(2) of the Implementing Regulation)'* without mentioning the wording of paragraph 4 of the same section reading *'Factors for registrants to consider when agreeing on the proportion of the contribution to the costs include, for example, their tonnage band or whether the request for information under substance evaluation relates to exposure or a specific use'.* The Claimant also referred to decision A-005-2014 of the ECHA Board of Appeal (hereinafter 'BoA') where the BoA in its decision in paragraph 86 *'considers that if data gaps in registration dossiers could be filled through substance evaluation and directed at several registrants of a substance, regardless of the tonnage registered and the type of registration made, with the associated consequences for cost sharing, this could undermine the balance achieved in the legislation, for example between cost and information. Filling a standard information requirement through substance evaluation could lead to significant costs for low tonnage and intermediate registrants who would not be exposed to such costs if the standard information had been provided through a registration by a higher volume registrant. The Agency should not therefore without clear justification, in effect, extend the standard information requirements'.*[24]

In their reply of 3 January 2018, the Other Party responded that whereas the Claimant sees the substance evaluation studies as tonnage related *'[the Other Party] see[s] it as a to be or not to be situation'*. The Other Party underlined that they had many internal discussions whether to go on with the registration of the substance in light of the substance evaluation decision and that *'if [they] had given up [their] registration then any new registrant of the substance would have needed to do these studies anyway since it was not a compliance check but a CoRAP evaluation. Therefore, [they] see it as fair that the co-registrants share these costs'*.[25]

The Claimant replied on 5 January 2018 and noted that other co-registrants might have not objected to share the costs because the studies were required for their registration for the higher tonnage band, but the Claimant did not need Annex [redacted] studies for the [redacted] tonnage band. The Claimant stated that if they had been the only registrant for the substance, they would have appealed the ECHA decision on substance evaluation. They ask how the Other Party can justify their cost-sharing model in light of the wording of the BoA decision A-005-2014. Finally, they propose to pay for the Annex [redacted] studies and to be provided with

[20] The Claimant; 6 November 2017.
[21] The Other Party; 7 November 2017.
[22] The Claimant; 7 November 2017.
[23] The Other Party; 7 November 2017.
[24] The Claimant; 7 December 2017.
[25] The Other Party; 3 January 2018.

[redacted]

the token and the joint submission name to allow them to register *'in a timely manner'.*[26]

On 9 January 2018, the Other Party replied that all co-registrants were in the same [redacted] tonnage band range until one decided to upgrade to [redacted] tpa, and the Board of Appeal decision was seen as not relevant for the present situation, because the decision was for an Extended One-Generation Reproductive Toxicity Study. Regarding the Claimant's question about a possible appeal to the ECHA decision on substance evaluation, the Other Party replied that they did not believe there was *'any chance to appeal against that decision'*. The Other Party agreed that the issues should be solved *'in a timely manner'*.[27]

On 20 January 2018, the Claimant stated that the Lead Registrant was in [redacted] tonnage band when the substance evaluation was carried out, they also pointed out *'[t]he fact that other companies may have subsequently paid for data they do not need does not mean that [the Other Party's] data sharing model is fair'.* Regarding the relevance of the BoA decision A-005-2014, the Claimant considered that the missing endpoint from Annex [redacted] should have been asked by ECHA under compliance check rather than under substance evaluation and *'[the Other Party] cannot use an error by ECHA in ordering data to be provided under Substance Evaluation rather than Dossier Evaluation as justification for [redacted] to pay for Annex [redacted] data that it does not need'.* They as well informed that they have consulted with the [redacted] Helpdesk on the issues and they were advised to challenge the Other Party's proposal and negotiate on the costs. They inquired whether the Other Party could change *'its position and just charge [the Claimant] the cost of a Letter of Access for the Annex [redacted] data requirements'.*[28]

On 6 February 2018, the Other Party replied that, after having internal discussions as well as discussion with the co-study owner, they decided not to change their position regarding the LoA cost.[29]

On 8 February 2018, the Claimant expressed their disappointment that the Other Party was not considering a revision of the LoA cost. They noted that they had offered different options to the Other Party during the long-term ongoing negotiations period on the matter and asked whether the Other Party could *'offer any resolution other than having the issue be settled by ECHA through a data-sharing dispute'*. The Claimant requested for a reply within *'the next week'.*[30] The following day, the Other Party replied that they *'can't see any alternatives'*, agreed to a ruling from a third party and assured the Claimant that '*[i]f there is a problem with the upcoming deadline […] [they] can arrange something to make sure [the Claimant] register on time'*.[31] In return, the Claimant informed about their intention to lodge a data-sharing dispute to ECHA.[32]

The Claimant filed the dispute at ECHA and notified the Other Party on 16 February 2018.[33]

Assessment

According to Article 30(1) REACH, and as reinforced by the Commission Implementing Regulation (EU) 2016/9[34] (hereinafter the 'Commission Implementing Regulation'), the

[26] The Claimant; 5 January 2018.
[27] The Other Party; 9 January 2018.
[28] The Claimant; 20 January 2018.
[29] The Other Party; 6 February 2018.
[30] The Claimant; 8 February 2018.
[31] The Other Party; 9 February 2018.
[32] The Claimant; 9 February 2018.
[33] The Claimant; 16 February 2018.
[34] 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

[redacted]

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 terms of sharing the data in a fair, transparent and non-discriminatory manner. This means asking questions about any concerns and replying constructively to each other's questions and concerns, and using the exchange of information effectively in order to find a common understanding on which the cost sharing agreement can ultimately be based.

In order to support existing and potential registrants in their negotiations, the Commission Implementing Regulation introduced several elements that clarify the rights and obligations of the companies in their efforts to reach a fair, transparent and non-discriminatory agreement. In particular, the Commission Implementing Regulation stipulates the need for itemisation of the data to be shared, the itemisation and justifications of administrative costs, a reimbursement mechanism (Article 2(1) of the Commission Implementing Regulation), and a cost-sharing model including fair and non-discriminative *'provisions for sharing any costs resulting from a potential substance evaluation decision'* (Article 4(2) of the Commission Implementing Regulation). Additionally, Article 4(1) of the Commission Implementing Regulation also stipulates that *'any registrant of a substance shall only be required to share the costs of information that such registrant is obliged to submit to the Agency to satisfy his registration requirements'*.

Throughout the negotiations, both parties generally communicated in a timely and constructive manner. The Other Party responded to the Claimant's requests for information, namely provided the LoA costs and the prospective scenarios for LoA costs based on the change of number of co-registrants, the cost breakdown, the detailed study list and the SIEF agreement. The Claimant evidently considered the documents provided to them to be clear, comprehensible and sufficient for understanding the cost-sharing model implemented by the Other Party. Moreover, the Claimant accepted and, in their emails of 21 December 2016 and 5 January 2018, proposed to pay the administrative costs and the study costs indicated in the LoA and directly associated with the information requirements for their potential registration in [redacted] tonnage band. Thus, ECHA notes that both parties made efforts in negotiating on the major elements of data sharing. The sole disagreement concerning the sharing of costs between the parties relates to the costs resulting from a substance evaluation decision.

During the negotiations, the Claimant made efforts to progress the negotiations between the parties in order for them to come to a common understanding on whether the Claimant should participate in these costs, which result from a substance evaluation decision and describe a standard information requirement at Annex [redacted]. This effort is displayed in particular when the Claimant questioned the reference by the Other Party to the ECHA guidance on data-sharing, the Claimant's reference to the BoA A-005-2014 decision and its relevance for the negotiations and when the Claimant referred the question at hand to the [redacted] for guidance. Further, with no agreement on the sharing of costs related to the substance evaluation decision, the Claimant sought to come to an agreement between the parties by offering an interim resolution and lastly the Claimant gave the Other Party the option of proposing any useful solution to the disagreement.

On this basis, the Claimant consistently questioned why they had to pay the amount asked by the Other Party, arguing it was not fair that they had to pay the same as registrants in higher tonnage bands. The Other Party sought to provide an answer to the Claimant by referring to ECHA Guidance on data sharing. However, when the Claimant asked why the Other Party had not included the complete relevant wording of the text in their answer, where the guidance states that the parties need to come to an agreement on the sharing of costs taking into account for example their respective tonnage bands, the Other Party did not reply.

The Other Party categorically replied to the Claimant's concerns regarding the cost sharing as

[redacted]

a result of a substance evaluation that *'costs will be shared by all registrants equally and are not allocated to a volume band'*, justifying this approach by *'common use within SIEF leadership teams and consortia', 'the policy of [the Other Party]'* and general acceptance of the cost sharing model by the previous registrants.

During the negotiations, the Claimant made efforts to try to overcome the disagreement on the sharing of costs related to the substance evaluation by referring to the findings of the BoA in its decision A-005-2014 and explaining why the BoA decision is relevant for their case. The Claimant asked how the Other Party could justify their position in light of the wording in paragraph 86 of that decision. In reply to this, the Other Party confirmed that their view on the matter has not changed in light of the BoA decision. However, by simply rejecting the argument from the Claimant and not seeking a dialogue on the matter, by for example providing a more elaborate answer, the Other Party failed to help to progress the negotiations in light of the Claimant's efforts to come to a common understanding by referring to the BoA decision.

The Claimant also made efforts in the negotiations by referring the question at hand to the [redacted] Helpdesk, which advised the Claimant to challenge the position of the Other Party. When presented with this opinion [redacted], the Other Party did not provide any response, thereby failing to progress the negotiations in light of the efforts made by the Claimant.

To facilitate the negotiations, the Claimant also proposed to pay immediately the redacted LoA costs and postpone the *'discussion of compensation for the Annex [redacted] Substance Evaluation test […] to a later time'.* In their reply, the Other Party underscored, that the split of data and costs of a substance evaluation equally between all registrants complies with the Commission Implementing Regulation and that all current registrants have paid their equal share of the costs, thus there is no possibility for lowering the LoA fee for any company. The Commission Implementing Regulation stipulates that the parties need to discuss and agree on the cost sharing. The Other Party rejected the possibility to discuss this matter by ruling out any flexibility from the Other Party's side as to the price of the LoA, thereby consequently eliminating the possibility of a discussion and a compromise between the parties.

Finally, the Claimant, after long negotiations, showed willingness to come to any useful agreement by asking the Other Party whether they can offer any resolution other than having the issue settled at ECHA. The Other Party here got a possibility to facilitate the negotiations on their terms, however the Other Party replied after only one day that they do not see any alternatives to the proposal by the Claimant to have the dispute settled by ECHA, thereby not actively using this last effort proposed by the Claimant to come to an agreement.

Based on the above ECHA considers, that the Claimant made every effort during the negotiations to come to an agreement between the parties by questioning the reference by the Other Party to the ECHA guidance on data-sharing, by referring to the BoA A-005-2014 decision and its relevance for the negotiations and by referring the question at hand to the [redacted] for guidance. Further, the Claimant showed willingness to facilitate the negotiations by offering an interim resolution and asking whether the Other Party could *'offer any resolution'*. The Other Party provided answers to the Claimant, however the Other Party exempted the sharing of costs related to a substance evaluation decision from the data sharing negotiations by repeatedly rejecting to discuss any new or revised LoA price. In doing so, the Other Party demonstrated a lack of will to make the necessary efforts needed to find a fair, transparent and non-discriminatory agreement between the parties. Accordingly, ECHA concludes, that by having demonstrated flexibility, active participation in the negotiations and a real willingness to progress the negotiations and find a compromise between the parties, however being obstructed by the sole point of disagreement, the Claimant exhausted all possibilities to reach an agreement on data sharing and filed the present dispute as a measure of a last resort.

[redacted]

Conclusion

Based on the above, ECHA concludes that the Claimant made efforts to explain their concerns regarding the fairness of the cost-sharing model. By not being open to revise the cost-sharing resulting from substance evaluation decision, the Other Party did not make every effort to reach an agreement with the Claimant in a fair, transparent and non-discriminatory way, and the Claimant filed the dispute as a measure of last resort.

Consequently, ECHA grants the Claimant access to the joint submission and permission to refer to vertebrate data, specified in the Annex II of this decision, submitted by the Other Party.