[redacted]

Helsinki, 9 April 2018

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

Represented by

[redacted]

Decision number: [redacted]
Dispute reference number: [redacted]
Name of the substance: [redacted]
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 the 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 Annex IV.

b) Procedural history

[redacted]

Helsinki, 9 April 2018

On 17 January 2018, you (the 'Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with [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 6 February 2018.

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, 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

Despite the present decision, the parties are still free to reach a voluntary agreement. Accordingly, ECHA recommends that the parties negotiate further and continue their efforts to reach an agreement that will be satisfactory for both parties.

Please note that 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]

Helsinki, 9 April 2018

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 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 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 13 July 2009, the Other Party informed the SIEF members of the successful submission to ECHA of the registration dossier for the substance and asked about the registration intentions of the SIEF members.[3] The Claimant replied on 31 July 2009, asking about the cost of participation and asking to be kept up-to-date on the Other Party's activities.[4] During 2009 and 2010, several information emails were sent by the Other Party to the SIEF members.[5] On 12 October 2011, the Claimant informed the Other Party of their pre-registration and their tonnage band [redacted]. Referring to the cost for the Letter of Access ('LoA') on the Other Party's website, they asked whether there had been an '*upgrade of this price*'.[6] The Other Party indicated that the cost had not changed.[7]

There was an interval of 5 years before the Claimant contacted the Other Party again, on 26 July 2016, requesting a LoA for [redacted] tonnage band[8]. The Other Party provided the SIEF agreement and the draft LoA the following day.[9] The Claimant replied on the same day and asked for the '*1. itemisation of the data and their costs 2. itemisation and justification of the administrative costs 3. cost-sharing model, which include a reimbursement mechanism*', '*according to Commission Implementing Regulation (EU) 2016/9*'.[10] On 22 August 2016, the Other Party provided further information; in particular, they explained that '*[i]n calculating the price of the LoA, the [Other Party] has taken into account only the number of registrants who are likely to buy a LoA for the respective tonnage band*'. The Other Party further stated that a calculation of the expenses and revenues received by them would occur after the 31 May 2018 deadline or, if earlier, after a substance evaluation by ECHA; then '*the co-registrants will be informed about possible reimbursements or additional payments to be made*'. They also indicated, among others, that '*a 15% risk surcharge [….] [is] applied to the costs of each study*'.[11]

The Claimant contacted the Other Party 12 months later, on 30 August 2017, and asked whether the cost for the LoA had been updated '*according to Regulation (EU) 2016/9*'.[12] The Other Party replied on 31 August 2017 that the cost for the LoA would be recalculated after the 2018 deadline due to the unknown number of new registrants.[13] The Claimant replied on

[3] Other Party; 13 July 2009.
[4] Claimant; 31 July 2009.
[5] Information letters were provided as part of the evidence by the Other Party.
[6] Claimant; 12 October 2011.
[7] Other Party; 13 October 2011.
[8] Claimant; 26 July 2016.
[9] Other Party; 27 July 2016.
[10] Claimant; 27 July 2016.
[11] Other Party; 22 August 2016.
[12] Claimant; 30 August 2017.
[13] Other Party; 31 August 2017.

[redacted]

Helsinki, 9 April 2018

the same day that, although they understood that *'near the 2018 deadline it may be expected to wait for a recalculation'*, it seemed like there had not been *'any recalculation of the cost of the [LoA] already after the first deadline of 2010.'*[14] On 18 September 2017, the Claimant asked whether any recalculation of the LoA cost was done after the 2010 and 2013 registration deadlines.[15] The Other Party replied that their current cost sharing model was under evaluation due to the Commission Implementing Regulation and the new version of ECHA's data-sharing Guidance. They further indicated that *'[i]t is possible that the current cost model will be revised and, as a result, every affiliate of a company group will need to purchase an individual LoA'*. Finally, they stated again that due to the upcoming deadline and the unknown number of registrants, they would recalculate the LoA cost after the expiry of the 2018 registration deadline.[16]

On 20 September 2017, the Claimant noted that the Commission Implementing Regulation had been in force for 20 months and would have been in force for nearly 30 months by the 2018 deadline. They further stated that the REACH Regulation already foresees a *'breakdown of costs'* and that they understood that no *'breakdown of costs […] between coregistrant[s]'* was done after the 2010 and 2013 registration deadlines. Finally, they claimed that the Other Party's data-sharing model was not fair and transparent.[17]

On 22 September 2017, the Other Party responded that even though the Commission Implementing Regulation came into force in January 2016, ECHA's updated Guidance on data-sharing was only published in January 2017. They indicated that the Commission Implementing Regulation required *'extensive changes to the cost sharing model applied by [the Other Party] so far'* and that *'the work associated with the recalculation exercise is considerable and highly complex'*. The Other Party stated that they *'[had] decided to postpone the communication of a new LoA price to the middle of 2018'* due to the unknown number and identity of all the co-registrants.[18]

On 10 October 2017, the Claimant said that they were awaiting a reply as to why no cost breakdown had been done since 2010.[19] The Other Party responded that they had replied on 22 September.[20] The Claimant replied that they did not consider the reasons given, in particular the publication date of ECHA's Guidance on data-sharing, as acceptable justifications to postpone the application of the Commission Implementing Regulation. They stated that they considered it not transparent, fair or in line with the Commission Implementing Regulation that the *'breakdown [was] never performed of the LoA cost'*.[21]

After the Other Party acknowledged receipt of the previous email[22], the Claimant emailed on 23 October 2017 and expressed their regret that *'there is no possibility of constructive dialogue.'* They claimed that the documents previously received from the Other Party were not in compliance with Commission Implementing Regulation, in particular because the costs and a 15% risk surcharge applied to the study costs were not justified. The Claimant asked the Other Party once again to confirm whether they had the intention to implement the Commission Implementing Regulation before the 2018 registration deadline.[23]

The Other Party replied on 26 October 2017 by proposing a conference call at a specific time

[14] Claimant; 31 August 2017.
[15] Claimant; 18 September 2017.
[16] Other Party; 18 September 2017.
[17] Claimant; 20 September 2017.
[18] Other Party; 22 September 2017.
[19] Claimant; 10 October 2017.
[20] Other Party; 10 October 2017.
[21] Claimant; 10 October 2017.
[22] Other Party; 19 October 2017.
[23] Claimant; 23 October 2017.

[redacted]

Helsinki, 9 April 2018

with the Claimant.[24] The Claimant replied on 30 October 2017 that they were unavailable at the proposed time and, before agreeing to a conference call, they asked about the proposed discussion topics. They further asked whether the Other Party had the intention of implementing the Commission Implementing Regulation before the 2018 registration deadline. If the Other Party did not have this intention, the Claimant ' *[did not] understand what […] to discuss'*; in case they did, they asked the Other Party to '*write [to the Claimant] which implementation will be done and when'*.[25]

The Claimant sent a reminder on 17 November 2017, requesting a reply.[26] The Other Party responded on 21 November 2017 by reiterating that the LoA cost would be recalculated after the 2018 deadline. They attached five PDFs giving information on the study and administrative costs in order to show to the Claimant '*a full traceability of all costs incurred in connection with the joint submission'* for the substance. They noted that they are *'currently working on a revised cost-sharing model which will also include a reimbursement mechanism'*, but that they '*cannot currently share this model with [the Claimant] as [they] are waiting for the last wave of registrations in connection with the upcoming last registration deadline in May 2018 to know how many co-registrants there will be*'. They stated that they understood their justifications may not be fully satisfactory to the Claimant, but asked for the Claimant's understanding in view of the need for the Other Party to put efforts '*on finalizing the cost sharing model as well as the preparation of the upcoming substance evaluation of [the substance]'*.[27]

The Claimant replied on 22 November 2017 and emphasised that their request for a recalculation of the LoA cost before the 2018 deadline was '*motivated by the attempt to have a lower money exposure for [their] company'*, and that the '*cost of LoA for a substance is an important aspect that [the Claimant] must evaluate in order to decide [their] interest in the trade of that substance*'. They wrote that '*after so many request[s] to [the Other Party] to comply with Regulation (EU) 2016/9, [their] only chance […][was] opening a data sharing dispute'.*[28]

The Other Party responded the following day by proposing again a teleconference call and stated that *'[they] remain open to discuss the terms and conditions of the letter of access'*.[29]

On 28 November 2017, the Claimant thanked the Other Party for the proposal of a teleconference, but indicated that their concerns were not about '*how the [Commission Implementing Regulation] was applied by the [Other Party]'* nor '*about the ways in which LoA should be structured, but the question is that [the Other Party] has not implemented [the Commission Implementing Regulation] yet'*. They further stated that *'as of [the Other Party's] admission, [the recalculation] will happen in 2018 after the registration deadline'* and '*could be on late 2018 or 2019, or 2020'.* They indicated that they had asked several times for a recalculation of the LoA costs based on the previous registration deadlines of 2010 and 2013 and that the Other Party '*never made that calculation'.*[30]

On 17 January 2018, the Claimant referred to the Other Party's '*decision to postpone the implementation of [the Commission Implementing Regulation] after registration deadline 2018*'. They reiterated that they considered that the breakdown of costs was '*not in compliance by the law in force'* and that the reasons of the Other Party for not having yet conformed with it were not acceptable. In this same email, the Claimant notified the Other

[24] Other Party; 26 October 2017.
[25] Claimant; 30 October 2017.
[26] Claimant. 17 November 2017.
[27] Other Party; 21 November 2017.
[28] Claimant; 22 November 2017.
[29] Other Party; 23 November 2017.
[30] Claimant; 28 November 2017.

[redacted]

Helsinki, 9 April 2018

Party of its intention to file a dispute to ECHA.[31]

The Claimant filed the dispute to ECHA on the same day.

Assessment

According to Article 30(1) REACH, and as reinforced by the Commission Implementing Regulation (EU) 2016/9[32] (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 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 indicates that transparency implies that a data-sharing agreement shall include a '*clear and comprehensible […] cost-sharing model, which shall include a reimbursement mechanism*' (Article 2(1)(c) of the Commission Implementing Regulation). Pursuant to Article 2(3) of the Commission Implementing Regulation, where there are several registrants for the same substance, the reimbursement mechanism shall include '*a record of any compensation received from new registrants*'.

Making every effort requires existing registrants to take into account references made by potential registrants to the Commission Implementing Regulation; part of making every effort also implies to provide on request a transparent cost-sharing model with a reimbursement scheme in the data-sharing agreement.

Throughout the negotiations, both parties generally communicated in a timely manner. The Other Party pro-actively gave information on the study and administrative costs and provided further information on those on request of the Claimant. However, the main point of disagreement in the negotiations related to the request by the Claimant for a recalculation of the cost of the LoA and the update of the cost-sharing model, taking into account the actual number of registrants following the 2010 and 2013 registration deadlines and the Commission Implementing Regulation. In the negotiations, the Other Party indicated that a recalculation would occur after the 2018 registration deadline, referring to the unknown number of registrants for this deadline and, more broadly, to the complexity of the exercise of revising their cost-sharing model following the Commission Implementing Regulation.

Regarding the unknown number of co-registrants, the Other Party explained in their letter of 22 August 2016 that they calculated the cost of the LoA based on '*the number of registrants who are likely to buy a LoA for the respective tonnage band'*. During the negotiations, they confirmed that the proposed cost for the LoA in 2017 was the same as in 2009 and informed that they would recalculate the cost after the 2018 registration deadline. The Claimant expressed concerns with this approach, which they found not transparent in view of the REACH Regulation and of the Commission Implementing Regulation.

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[31] Claimant; 17 January 2018.

[32] 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).

[redacted]

Helsinki, 9 April 2018

When requested by a potential registrant, an existing registrant must provide transparency on the sharing of costs among registrants, in particular to allow the potential registrant to assess whether the cost-sharing model is fair and non-discriminatory toward them. During the course of the negotiations, the Other Party did not provide information on the number of existing registrants, on the way they had estimated their number in 2010 nor on whether this number had evolved since then. The Other Party's answers continually referenced the unspecified number of registrants for the 2018 deadline, without replying to the Claimant's specific questions and concerns on the lack of transparency on the division of costs among registrants. This prevented the the Claimant from assessing the fairness and non-discriminatory character of their cost-sharing mechanism. By doing so, despite the repeated questions by the Claimant, the Other Party failed to take into account the Claimant's concerns and to make every effort to find a transparent agreement.

The Claimant further challenged the conformity of the Other Party's cost-sharing model with the Commission Implementing Regulation, in particular by questioning the transparency of the sharing of costs between registrants and the motivation of the addition of a 15% risk surcharge to the study costs. The Other Party explained during the negotiations that they were planning a revision of their cost-sharing model in view of the Commission Implementing Regulation, possibly involving a change in the approach regarding affiliates of company groups and the creation of a reimbursement mechanism. They further indicated that they could not provide further details on this new cost-sharing mechanism to the Claimant and that the latter would be informed after the 2018 registration deadline.

The Claimant raised concerns on this approach and pointed out that the Commission Implementing Regulation entered into force already in January 2016. They also explained that this situation made it difficult for them to evaluate their interest in trading the substance before registering it. During the negotiations, the Other Party justified the delay in communicating the new cost-sharing mechanism by referring to the amount of work requested by the update of the cost-sharing model, to the update in January 2017 of ECHA's Guidance on data-sharing and to a future substance evaluation on the substance.

The Claimant rejected these justifications, considering them as not acceptable for not conforming to the Commission Implementing Regulation and postponing its implementation to after May 2018. The Other Party did not further reply to this challenge and repeated their previous justification.

By stating that the implementation of the Commission Implementing Regulation required '*extensive changes to [their] cost sharing model*', the Other Party implicitly recognized that this model was not in line with it and had to be revised. However, they did not provide further details on the future cost-sharing model. By doing so, the Other Party put the Claimant in the position of paying for a LoA without knowing the cost-sharing model and reimbursement scheme that will be applied to it.

Making every effort means that existing registrants need to address the request by potential registrants for having a data-sharing agreement based on a transparent cost-sharing model with a reimbursement scheme, as foreseen by the Commission Implementing Regulation. By not addressing the Claimant's request for being transparently informed on the cost-sharing model and a reimbursement scheme according to the Commission Implementing Regulation before signing the data-sharing agreement, the Other Party showed a lack of efforts to find a fair, transparent and non-discriminatory agreement.

Against this background, ECHA notes that the Other Party proposed twice to the Claimant to hold a teleconference. The Claimant refused, asking for the topics for discussion and indicating that they did not see the need for a phone call in case the Other Party was not willing to implement the Commission Implementing Regulation before the 2018 registration deadline. Proposing to hold a teleconference can constitute efforts in the negotiations, since it may help the parties progressing with their negotiations and solving points of disagreement. However,

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Helsinki, 9 April 2018

the Other Party did not provide further details on the topics to discuss and repeated that the new cost-sharing model implementing the Commission Implementing Regulation would be communicated after the 2018 deadline only, i.e. that it would not be communicated as part of the data-sharing agreement to be signed by the Claimant. Therefore, the proposal for a phone call does not outweigh the Other Party's failure to provide the requested transparent cost-sharing model to the Claimant before signing the data-sharing agreement.

Conclusion

Based on the above, ECHA concludes that the Claimant made efforts to explain their concerns regarding the transparency of the cost-sharing model and its compliance with the Commission Implementing Regulation, as well as the difficulties for them in case of postponement of the update of this model after the 2018 registration deadline. By not addressing the request and concerns raised by the Claimant on these points, the Other Party did not make every effort to reach an agreement with the Claimant in a fair, transparent and non-discriminatory way, as required by the Commission Implementing Regulation, 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.