[redacted]

Helsinki, 26 April 2018

The Claimant

[redacted]

Represented by

[redacted]

Copy to:
The Other Party

[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

On 6 February 2018, you (the 'Claimant') submitted a claim concerning the failure to reach

[redacted]

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 27 February 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 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 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 10 October 2017, the Claimant's representative contacted the Other Party, who is the Lead Registrant for the substance, to notify them of the Claimant's intention to register the substance for the tonnage band [redacted] The Other Party replied the same day and stated that the estimated cost for the Letter of Access ('LoA') was [redacted] euros. They also asked the Claimant to register on the Other Party's website portal.[4]

On 29 October 2017, the Claimant requested the cost model within 5 working days, as indicated on the Other Party's website, and noted that they '*presuppose[d] the provided cost model will be compliant with the Commission Implementing Regulation (EU) 2016/9 in detail acc. to Article 2.*'[5] The Other Party responded the next day by providing the cost breakdown, listing the research and summary costs, study costs, [redacted] *and dossier costs'*, and administration costs that made up the previously mentioned LoA cost.[6]

The Claimant requested further explanation on 1 November 2017 of some of the calculations and costs. They noted inconsistencies between the provided cost breakdown and the registration dossier as visible on the dissemination portal, such as study costs claimed in the cost breakdown that in the disseminated information were shown to be waivers. They also pointed out a cost for an endpoint that was not required by Annex [redacted] i.e., irrelevant for their registration in [redacted]. The Claimant said that the [redacted] *and dossier cost*' was '*hard to follow'* and asked for an explanation for the item '[redacted] – [redacted] €'. They also questioned the overall administration costs of €[redacted] per registrant, and asked: '*Please explain the calculation […] in detail. Your administrative overall costs would be* [redacted] *x* [redacted] *€ =* [redacted] *€.*'[7]

The Other Party responded on 13 November 2017. They explained that ongoing study endpoints would be '*updated soon*' with new studies; that the specified unrequired endpoint would be removed from the calculation; and that the '[redacted] *and dossier cost*' was for the '*cost towards the admin activities conducted by the lead till 2018, such as responding to the elaborate queries from the SIEF members and answering their individual queries etc.*' Regarding the administration costs, they re-sent the justifications given in the previously provided cost breakdown. They added that '*This is the overall admin cost and if more than 5 members joins the joint submission then this cost will be also further reimbursed to the joint registrants accordingly.*'[8]

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[3] Claimant; 10 October 2017.
[4] Other Party; 10 October 2017.
[5] Claimant; 29 October 2017.
[6] Other Party; 20 October 2017.
[7] Claimant; 1 November 2017.
[8] Other Party; 13 November 2017.

[redacted]

The Claimant sought further clarification on 29 November 2017 to ensure they understood the Other Party's explanations regarding endpoints, and asked to be informed of when the registration would be updated. They also queried the administration costs and said that '*Since we do not have any idea how to make administrative costs in sum* [redacted] *for a registration with* [redacted] *member registrants, we hope to meet you if we accept administrative costs of* [redacted] *€ without going further steps.*' They made a counter-proposal of [redacted] euros for the LoA, which took into account the new proposed administration costs and the removal of the unrequired endpoint as agreed to in the previous communication with the Other Party.[9]

The Claimant emailed on 11 December 2017 to request a reply to the previous communication within 10 days.[10] Having received none, they emailed again on 4 January 2018 and said that they '*kindly encourage[d]*' the Other Party to respond by 17 January 2018, otherwise they would '*pose this issue to the ECHA for solving*.'[11]

The Claimant filed the dispute with ECHA on 6 February 2018.

Assessment

According to Article 30(1) of REACH, and as reinforced by the Commission Implementing Regulation (EU) 2016/9[12] (hereinafter the 'Commission Implementing Regulation'), 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 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 implies to provide on request a transparent cost-sharing model with a reimbursement scheme in the data-sharing agreement.

Parties have an obligation to strive for a transparent and comprehensive data-sharing agreement. The Claimant made considerable efforts in this regard by analysing the cost breakdown provided by the Other Party, asking for clarification on the points they found incomprehensible, and comparing what was provided in the cost breakdown with the registration dossier that is disseminated on ECHA's website. Of particular concern to the Claimant were (i) a study that was not required for their tonnage band; and (ii) the administration costs.

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[9] Claimant; 29 November 2017.

[10] Claimant; 11 November 2017.

[11] Claimant; 04 January 2018.

[12] 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).

Regarding the study that was not required, ECHA acknowledges that both parties made efforts to reach an agreement: when the Claimant requested the Other Party to remove said endpoint from the LoA cost, the Other Party agreed to this. Consequently, the parties were able to reach an agreement on this matter in line with their obligation to make every effort in the data-sharing negotiations, but the parties were not able to come to an agreement regarding the administration costs.

The Other Party initially provided a description of the tasks covered by this cost item. However, despite repeated requests from the Claimant to clarify the cost model and total cost given, the Other Party responded by simply copying and pasting the paragraph concerning administration costs from the previously provided cost breakdown, instead of specifically engaging with the Claimant's concerns. The Other Party attempted to lessen those concerns by stating that '*This is the overall admin cost and if more than 5 members joins the joint submission then this cost will be also further reimbursed to the joint registrants accordingly*.'; however, no reimbursement mechanism was provided to confirm this.[13] This prevented the Claimant from assessing the fairness and non-discriminatory character of any cost-sharing mechanism. This meant that despite repeated concerns raised by the Claimant regarding the cost breakdown, the Other Party did not provide an answer to the Claimant that would allow the Claimant to understand how the administration costs were calculated. In the absence of such clarifications that would have allowed the Claimant to objectively understand this cost item, they made additional efforts by making a counter-proposal for the administration costs based on their own estimates and experiences. However, the Other Party neither came back to this counter-proposal nor did they provide the requested clarification. Thereby, the Other Party failed to take into account those concerns and to make every effort to find a transparent agreement.

Making every effort also means to reply to the questions and concerns raised by the negotiation partner in a timely manner. The lack of reply to both the counterproposal sent by the Claimant on 13 November 2017 and the Claimant's email reminders indicate that the Other Party did not fulfil their obligation to communicate in a timely and helpful manner. Hence, they did not make every effort to reach an agreement on data costs with the Claimant and by this, they failed to make any effort to continue productive negotiations with the Claimant, while the Claimant remained active and made efforts.

Conclusion

Based on the above, ECHA concludes that the Claimant made every effort by explaining their concerns to the Other Party regarding the provided breakdown of costs and why the administration costs were, to their mind, not justifiable. They made further efforts by making a counter-proposal for the administration costs, and by reminding the Other Party of open questions. By not addressing or engaging specifically with the concerns raised by the Claimant, and by not responding to the Claimant's emails from 13 November 2017 until the dispute was filed, 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.

[13] Other Party; 13 November 2017.