[redacted]

Helsinki, 23 March 2018

The Claimant

[redacted]

Copy to:
The Other Party

[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') [1],

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 5 January 2018, you ('the Claimant') submitted a claim concerning the failure to reach an agreement on the access to joint submission with [redacted] ('the Other Party') as well as the related documentary evidence to ECHA. To ensure that both parties

[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.

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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. On 26 January 2018, the Other Party provided a letter by which they explained their position to ECHA accompanied by documentary evidence consisting of a single e-mail. For the purpose of the Agency's assessment of whether every effort is made to reach an agreement, only documents that have been exchanged between the two parties were taken into account[2].

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.

Yours sincerely,

Christel Schilliger-Musset[3]

Director of Registration

[2] Decision of the Board of Appeal of ECHA of 17 December 2014 in Case A-017-2013, *Vanadium*, paragraph 99.

[3] 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]

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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 assesses 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

The Claimant initiated the negotiations on 9 November 2017, requesting the Other Party to inform them of the conditions and steps to receive a Letter of Access (LoA).[4] On 15 November, after clarifying the Other Party's question[5] regarding the subsidiary, on whose behalf they were requesting such information, the Claimant requested a price quotation for the LoA for the tonnage band [redacted].[6]

With their message of 23 November 2017, the Other Party provided the price and stated that the price was not tonnage band specific, i.e., the same price was applicable for all tonnage bands.[7] The Claimant replied on the same day, requesting a detailed breakdown of the provided LoA costs, *'including an explanation of how these total costs were calculated'*. They emphasised that *'the distribution of costs must be fair, transparent and non-discriminatory'* and that *'each item must be substantiated and the price must relate to the information [they] need for [their] registration'*. Further, they requested *'as an alternative'* the price of the token in the case of an opt-out for all data.[8]

On 19 December 2017, the Claimant contacted the entire SIEF membership (including the Other Party), explaining that they had received a flat price for the LoA and inquired whether any of the members had received additional information from the Other Party regarding data and whether they had successfully shared data. Further, they asked whether the SIEF members were willing to support the Claimant in their efforts to reach an agreement or submit jointly a data-sharing dispute in case they were facing the same issues.[9]

On the same day, the parties held a teleconference, which was, according to the Claimant, '*suddenly terminated*' by the Other Party. The Claimant sent a message to the Other Party, after the teleconference requesting a cost breakdown for the tonnage band [redacted] and set the deadline for the Other Party to reply by 31 December 2017. Further to this, the Claimant stated that in absence of a reply they would file a data-sharing dispute with ECHA not to *'jeopardise'* their obligation to register [redacted].[10]

On 5 January 2018, the Claimant filed the dispute for the data required for a registration at the tonnage band of [redacted].

[4] Claimant, 9 November 2017
[5] Other Party, 15 November 2017
[6] Claimant, 15 November 2017
[7] Other Party, 23 November 2017
[8] Claimant, 23 November 2017
[9] Claimant, 19 December 2017
[10] Claimant, 19 December 2017

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Assessment

In accordance with Article 30 of the REACH regulation and Articles 2 and 4 of the Commission Implementing Regulation on joint submission of data and data-sharing (hereinafter 'CIR'), a potential registrant has the right to receive an itemisation of the costs related to data and administration. Such information is crucial to enable meaningful data sharing negotiations, as a potential registrant is not in a position to objectively assess and understand the data and the corresponding costs otherwise. It enables the potential registrant to assess whether the requested compensation is fair, transparent and non-discriminatory, as required by REACH and the CIR, as well as to assess the relevance of the jointly submitted data.

Further, according to Article 2 of the CIR, upon request of a potential registrant, the existing registrants need to provide proof of the cost of any study and '*make every effort to provide itemisation of all other relevant costs, including administrative costs and study costs* […] *without undue delay*'.

Moreover, Article 30(1) of the REACH Regulation and Article 4(1) of the CIR stipulate that registrants are only required to share the costs of information they need to fulfil their registration requirements. This means that registrants need to share the costs that relate to their information requirements, considering the tonnage band they intend to register. This applies to both study and administrative costs.

On 15 November 2017, the Claimant inquired the price of the LoA for the tonnage band [redacted] The Other Party provided the price informing that it '*was not tonnage band specific*'[11]. The Claimant objected to the same price for all tonnage bands, arguing that '*the price must relate to the information [they] need for [their] registration*'[12]. In addition, the Claimant requested a detailed breakdown of the provided LoA costs '*including an explanation of how these total costs were calculated*'[13]. As explained above, this is in line with the Claimant's rights under the CIR as a potential registrant. By asking further information regarding the calculation of the cost and explaining the legal requirements to the Other Party, the Claimant showed their intention and made efforts to progress the negotiations and reach an agreement.

The Other Party merely quoted a price for the letter of access, and did not even adjust this price according to the data requirements. By offering the same price for all tonnage bands, the Other Party did not take into account the Claimant's specific request nor the Claimant's right to share only the costs related to their tonnage band to reach a fair, transparent and non-discriminatory agreement as required by REACH.

To progress the negotiations, approximately one month after having requested the cost breakdown, the Claimant established a teleconference with the Other Party. The Other Party, according to the Claimant, suddenly ended the teleconference, leaving the Claimant's questions unanswered. Thus, also this new request from the Claimant to reach an agreement remained unaddressed.

Directly after the teleconference, the Claimant sent a message requesting the breakdown for a different tonnage band, [redacted], and set the deadline for the Other Party to reply by 31 December 2017. The Other Party did not reply, and the Claimant submitted the dispute on 5 January 2018. The time between the request for a cost itemisation for the higher tonnage band and the dispute submission was short. However, the Other Party did not indicate that they needed more time to reply nor did they request clarifications on the Claimant's request, as is their obligation to make every effort to reach an agreement.

[11] Other Party, 23 November 2017

[12] Claimant, 23 November 2017

[13] Claimant, 23 November 2017

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Instead, the Other Party remained silent and thus did not fulfil this obligation.

ECHA notes that the Claimant made clear requests and sent reminders to receive the cost breakdowns and made the effort of explaining their right to an itemisation and a data sharing agreement covering only their requirements under the CIR. On the other hand, the Other Party did not comply with their obligation under the CIR to provide a cost breakdown without undue delay and made it impossible for the Claimant to assess and discuss their cost offer. They never put the Claimant in a position to understand what they should pay for or why the data would come at this cost. The Other Party thus did not make the effort to establish the very starting point for meaningful negotiations on data and cost sharing. This, too, was a failure to make every effort.

In these circumstances, the short time between the Claimant's request for a cost itemisation at the higher tonnage band and the submission of the dispute is less relevant for the parties' failure to find an agreement. As mentioned above, after receiving Claimant's request to provide the cost itemisation for the higher tonnage band, the Other Party did not request clarifications nor did they indicate that they needed more time to accommodate the request. Moreover, they never replied to the Claimant's request for an itemisation at the [redacted] tonnage band, which was requested on 23 November 2017. Thus, there is no indication from the negotiations that the Other Party was going to provide a cost breakdown nor a tonnage band-specific LoA price.

Further to this, ECHA takes account of the fact that [redacted] the obligation under CIR to provide a cost itemisation upon request without undue delay had been in place since January 2016. To make every effort, the Other Party should have taken this urgency into account and provided a cost breakdown without undue delay.

Therefore, in the balance of the efforts, ECHA finds that the Claimant made more efforts than the Other Party to find an agreement.

Conclusion

Taking into account the above, ECHA concludes that the Other Party failed to make every effort to reach a fair, transparent and non-discriminatory agreement by (i) offering a flat price for all tonnage bands and (ii) not showing efforts towards providing the itemised breakdown of the LoA costs requested by the Claimant. On the other hand, the Claimant made more efforts to reach an agreement by making clear requests to receive a cost breakdown and in addition explaining their rights to share only costs relating to their information requirements. Therefore, ECHA grants a permission to refer to the requested vertebrate data in the tonnage band [redacted] and access to the joint submission.