[redacted]

Helsinki, 9 April 2018

The Claimant

[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 Articles 30(3) and 11 of Regulation (EC) No 1907/2006 ('REACH Regulation')[1] and Article 3 of the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH ('Commission Implementing Regulation')[2],

ECHA grants you the permission to refer to the information you requested from the Existing Registrant, [redacted], of the above-mentioned substance, and access to the joint submission.

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 to along with copies of (robust) study summaries can be found in Annex

[1] Regulation (EC) N° 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.

[2] 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), *OJ* L 3, 6.1.2016, p.41.

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II and III, respectively. Instructions on how to submit your registration dossier are provided in Annex IV.

b) Procedural history

On 21 December 2017, you ('the Claimant') submitted a claim concerning the failure to reach an agreement on data sharing and on access to the joint submission 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 31 January 2018. Only exchanges of information between the two parties were taken into account for the assessment of every effort[3].

Following a translation request of the Other Party on the basis of Regulation No 1 of 15 April 1958[4], the present decision will also be made available in [redacted] language.

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[5]

Director of Registration

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

[4] Council Regulation No 1 determining the languages to be used by the European Economic Community, *OJ* 17, 6.1.1958, p.385-386.

[5] 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.

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Annex I: REASONS OF THE DECISION

According to Article 11 of the REACH Regulation, all registrants of the same substance are part of the same registration under REACH ('joint submission'). Further, Article 3 of the Commission Implementing Regulation requires ECHA to ensure that all registrants of the same substance are part of the same registration for the substance.

The joint submission obligation is a collective responsibility of all registrants of the same substance. All registrants of the same substance are required to make every effort to find an agreement to register jointly.

In addition to the obligation to be part of the same joint submission, registrants of the same substance have an obligation to share data.

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.

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 in light of Article 5 of the Commission Implementing Regulation.

Factual background

On 24 November 2016, the Claimant requested the price of the Letter of Access (LoA) for the tonnage band [redacted][6] In the absence of any reply from the Other Party, the Claimant sent two reminders on 9 January 2017[7] and 16 March 2017.[8] On 20 March 2017, the Other Party provided an estimate for the LoA cost amounting to [redacted][9]

During April and June 2017, the parties discussed specifications of the boundary of the substance covered by the joint submission (substance identity profile (SIP)).

On 15 June 2017, the Claimant requested details on the LoA by 15 July 2017. In this email, the Claimant reminded the Other Party of the Commission Implementation Regulation's requirements regarding data and cost sharing, in particular a detailed cost breakdown of the shared data, a cost breakdown and justification of administrative costs as well as a cost sharing model including a reimbursement mechanism.[10]

On 16 June 2017, the Other Party asked confirmation of the purity of the Claimant's

[6] Claimant: 24 November 2016.
[7] Claimant; 9 January 2017.
[8] Claimant; 16 March 2017.
[9] Other Party; 20 March 2017.
[10] Claimant; 15 June 2017.

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substance.[11] On 7 July 2017, the Claimant confirmed the purity and asked once more for the current LoA cost.[12]

On 10 July 2017, the Other Party explained that the LoA contract would be prepared by their lawyer and it would be available after 8 August 2017.[13]

On 25 August 2017, the Claimant referred to a phone call where the parties had discussed the timeline for the contract and price of the LoA. In the email, the Claimant wrote, following their teleconference that they would like to have the discussed documents by 1 September 2017.[14] On the same day, 25 August 2017, the Other Party informed the Claimant that the lawyer responsible for the preparation of the contract was ill but that he promised to deliver the contract during the following week. They also told that the LoA price would not significantly change as there were no other potential registrants.[15] On 28 August 2017, the Claimant sent a reminder of the impending deadline, and asked the Other Party again for the LoA price.[16]

On 8 September 2017, the Claimant sent another reminder and provided three additional weeks to receive the requested documents (by 30 September 2017).[17] On 18 September 2017, the Other Party provided a contract for the Claimant's review.[18]

On 2 October 2017, the Claimant pointed out the absence of costs itemisation in the provided contract. They asked to receive a complete LoA contract including the appropriate costs itemisation by 15 October 2017. They also asked whether the submission of the [redacted] was part of the joint submission. Given the approaching deadline under REACH, the Claimant stressed the urgency of the matter and announced that they would file a dispute to ECHA in case the Other Party failed to provide them with the full documents by the set deadline.[19]

On 12 October 2017, the Other Party sent a letter to the Claimant, where they stated that they included a contract to the letter. The Other Party also sent an itemisation of administrative costs and overall costs of the studies without robust study summaries, and an invoice amounting to [redacted] The Other Party informed the Claimant that, following the payment of the invoice, the Claimant would receive a token and [redacted] (to be completed with the Claimant's specific data). Regarding the calculation of the costs (administrative and studies), the Other Party explained that the costs had been divided by the number of registrants [redacted]. A total inflation cost of 0,98 % (2013-2017) and a handling fee of 5 % were added to the total price.[20]

On 25 October 2017, the Other Party provided an additional itemisation of the studies, and re-sent the cost breakdown of administrative costs.[21] On 22 November 2017, the Other Party sent a reminder of the payment.[22]

By letter dated 27 November 2017, the Claimant commented the costs itemisation, and

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[11] Other Party; 16 June 2017.
[12] Claimant; 7 July 2017.
[13] Other Party; 10 July 2017.
[14] Claimant; 25 August 2017.
[15] Other Party; 25 August 2017.
[16] Claimant; 28 August 2017.
[17] Claimant; 8 September 2017.
[18] Other Party: 18 September 2017.
[19] Claimant: 2 October 2017.
[20] Other Party; 12 October 2017.
[21] Other Party; 25 October 2017.
[22] Other Party; 22 November 2017.

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enclosed to their letter an eight-page document assessing the cost itemisations in detail. The Claimant expressed their surprise about the amount of the invoice compared to the initially proposed amount. They referred to an amount paid by another registrant for the same tonnage band, that was [redacted] The Claimant also stated that the Other Party might try to delay their registration. The Claimant argued the registration should be fair and transparent, and requested a LoA template including a full list of the studies used in the dossier. They also asked further information on the contracts concluded for the purchased studies, on the travel expenses charged in the LoA cost, on the activities listed under the section 'external experts' as well as on the future costs. The Claimant set a deadline to receive this information by 15 December 2017.[23]

On 15 December 2017, the Other Party replied firstly that their LoA cost itemisations were prepared by their consultant in such way that every registrant would pay a fair share of the total costs. They explained that the costs were divided by the number of registrants in the tonnage band [redacted], and included an inflation and a handling fee. In attachment, they provided the same itemisation of administrative costs as the one sent on 12 and 25 October 2017 and a study cost itemisation identical to the one sent on 25 October 2017. Secondly, in order to explain the increase, the Other Party indicated that they had had to create a new SIEF agreement and revise their cost calculations, which were time consuming. The Other Party further explained that they have received requests for the LoA also from other companies, specifying that a contract was being concluded with a fifth registrant and negotiations were ongoing with two other potential registrants. The Other Party refused to provide any further information on travel costs. Regarding the contracts concluded for the purchased studies, the Other Party refused to provide further information without proof, for example, that it would have been cheaper to conduct studies in another laboratory. The Other Party also acknowledged the absence of a refunding mechanism, but stated that one would be put in place in 2018. Finally, on future costs, the Other Party argued that they could not predict the possible information requests by ECHA in the future.[24]

On 19 December 2017, the parties had a teleconference to understand the increase of the LoA price. The Claimant referred to the teleconference in their message to the Other Party on 20 December 2017. In this email, the Claimant expressed that they were astonished by the discussion, where the Other Party had explained that the Claimant was charged more for the LoA because they made the request earlier than the other potential registrants did. According to the Claimant, the Other Party had explained that there would be a reimbursement scheme at a later point of time. The Claimant also claimed in the email the Other Party had not commented on the arguments the Claimant had made in their letter on 27 November regarding the price of the LoA and the cost itemisation. The Claimant also indicated that, in their view, the LoA price (divided by the number of other registrants the Other Party had told had registered or with whom they were negotiating) should correspond to the initial offer of [redacted] Finally, the Claimant informed the Other Party of their intention to file a dispute, since they were uncomfortable with the Other Party's explanations.[25]

On 21 December 2017, the Claimant filed the dispute to ECHA.

Assessment

The documentary evidence provided by the parties included some exchanges with regards to another substance than substance [redacted] It also included exchanges regarding the tonnage

[23] Claimant; 27 November 2017.
[24] Other Party; 15 December 2017.
[25] Claimant; 20 December 2017.

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band [redacted]. As the subject-matter of the negotiations switched to the tonnage band [redacted], only efforts relating to the access to the joint submission of this substance and for the sharing of data for the tonnage band [redacted] of this substance are taken into account for the purpose of this assessment.

Making every effort to reach a fair, transparent and non-discriminatory agreement on sharing of data and costs means that existing registrants are required to provide to potential registrants, upon request, an itemisation and justification of all relevant costs to be shared, both data-related and administrative costs. This obligation has been further reinforced by the Commission Implementing Regulation (EC) 2016/9 on joint submission of data and data sharing, which sets out criteria aiming at facilitating data sharing between existing and potential registrants, helping the potential registrants to understand cost calculation and thus enabling the parties to engage in meaningful data sharing negotiations.

Making every effort also requires the parties to negotiate on sharing of data and costs as constructively as possible, to make sure that the negotiations move forward swiftly by expressing their arguments and concerns, and by replying to each other's questions and arguments. Moreover, where a party announces a price and that this price significantly increases, providing explanations is part of making every effort.

Firstly, during the negotiations, the Claimant sent multiple reminders and set numerous deadlines highlighting on several occasions their urgency to register. [redacted]), the Other Party could not ignore that the Claimant was under an objective urgency to progress with their registration [redacted]. As a general rule, when existing registrants see that the potential registrant needs to register urgently, they must take this into account, and not delay sending crucial information on data and costs.

Secondly, it took approximately four months for the Other Party to reply to the Claimant's requests on the LoA price and detailed itemisation of costs for the tonnage band [redacted]. The Claimant requested a LoA price on 24 November 2016. The Other Party provided an estimated price amounting to [redacted] on 20 March 2017. On 25 August 2017 they gave the assurance to the Claimant that this price would not significantly change. However, the final price amounted to [redacted] including tax), that is approximately 2,5 times higher than the amount initially announced. The Other Party did not inform the Claimant about this final price until they sent the invoice to the Claimant on 12 October 2017. The invoice was accompanied by a cost itemisation, which had been requested by the Claimant four months earlier (by email sent on 15 June 2017).

Given the difference of prices, ECHA considers that the Other Party failed in making particular effort in explaining the increase. Moreover, given the elapse of time in providing the requested information, ECHA considers that the Other Party failed in taking the urgency of the Claimant into account.

After the Other Party provided the detailed cost itemisation of the LoA, the Claimant commented it in a detailed analysis made by their consultant. They asked for further information in relation to the nature of certain costs (such as the travel expenses, external experts as well as contracts for the purchased studies) and asked further explanations on the increased price of the LoA. In response, the Other Party merely re-sent the same cost calculations they had previously given. They refused to give more details on the nature of certain costs on the ground that the Claimant should put forward suspicion. However, the obligation to provide to potential registrants, upon request, an itemisation and justification of all relevant costs to be shared (both data-related and administrative costs) is not subject to any condition under the Commission Implementing Regulation. Repeating information already provided and refusing to provide more information indicate a lack of effort from the Other Party.

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Thirdly, with regard to the teleconference, both parties made some effort in attending and discussing. However, even after the teleconference, questions on the increase and details on the nature of certain costs remained unsolved. The submission of a dispute to ECHA was therefore a measure of last resort in order to enable the Claimant to register the substance by the deadline set under the REACH Regulation.

Overall, the delay in providing the requested information, the lack of explanations on the increase of prices and on the Claimant's analysis demonstrate that the Other Party did not make every effort in reaching an agreement with the Claimant.

Conclusion

Based on the above, ECHA concludes that the Claimant made more efforts than the Other Party in view of reaching an agreement on the sharing of data and their costs and on access to the joint submission as required by Article 30 of the REACH Regulation.

Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to vertebrate data, specified in the Annex II of this decision.