[redacted]

Helsinki, 24 October 2017

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 does not grant you the permission to refer to the information you requested from the Existing Registrant, [redacted], of the above-mentioned substance.

The reasons of this decision are set out in Annex I. Advice and further observations are provided in Annex II.

b. Procedural history

On 9 August 2017, you ('the Claimant') submitted a claim concerning the failure to reach an

[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.

[redacted]

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 30 August 2017.

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.

Yours sincerely,

Christel Schilliger-Musset[2]

Director of Registration

[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

The Claimant initiated the negotiations on 14 December 2016, informing the Other Party that they had pre-registered the disputed substance and requested a price quotation for a letter of access (LoA) for the tonnage band [redacted], the Substance Identity Profile (SIP) and other SIEF relevant information.[3]

On 19 December 2016, the Other Party provided the LoA price adding that the provided price was subject to a [redacted]% yearly surcharge, effective from January 1st, following the year of the dossier submission.[4] The Claimant replied on the same date, pointing out that the LoA price was '*extremely high'* and requested (i) a list of studies required per end-point with their corresponding value and their Klimisch score (ii) other cost items (iii) explanation for the [redacted]% increase and (iv) explanation of their cost sharing model.[5]

On 22 December 2016, the Other Party explained that the price reflected the '*total study costs for this substance'* and provided a '*cost overview'* of the LoA, consisting of the following categories: the total cost of studies, administrative costs and the yearly surcharge which equalled [redacted]% of the LoA price (as the period after the dossier registration equalled [redacted]years).[6]

The Claimant replied on 17 January 2017, that the provided information was not *'sufficient'* and pointed out that the Other Party's dossier included an OECD [redacted] study that was not required for their tonnage band and moreover was '*very expensive'*. In addition, they reiterated their earlier request for a detailed cost breakdown of the studies and their Klimisch score[7]. In their reply, the Other Party directed the Claimant to the ECHA website for a full list of the studies used in their dossier and added that the LoA includes only the costs of the required studies for their tonnage band. Furthermore, they explained that the OECD [redacted] study was not included in the LoA price.[8]

On 16 March 2017, referring to the Commission Implementing Regulation, the Claimant requested a detailed breakdown of the study costs, stressing that the dossier costs were three times higher than they should be for [redacted] studies. In addition, they reiterated again their disagreement with the [redacted]% surcharge and attached a non-disclosure agreement

[3] See the Claimant's message dated 14/12/2016
[4] See the Other Party's message dated 19/12/2016
[5] See the Claimant's message dated 19/12/2016
[6] See the Other Party's message dated 22/12/2016
[7] See the Claimant's messages dated 17/01/2017 and 08/03/2017
[8] See the Other party's message dated 10/03/2017

[redacted]

(NDA). The Claimant requested the information to be provided by 4 April 2017.[9] On 7 April 2017, after having signed the NDA, the Other Party provided the detailed breakdown of the study costs. With regard to the yearly surcharge, the Other Party explained that it would be part of the reimbursement process, to be recalculated after the 2018 REACH deadline.[10]

In their reply of 4 July 2017, the Claimant requested the Other Party to '*reconsider* [their] *cost allocation'* referring to the ECHA data sharing guidance. They raised the following main points concerning the provided breakdown: (i) given that there were already two legal entities registered, both should '*pay their share'* of the costs (ii) there should be only one key study per end-point and (iii) the dossier contains higher tier studies where lower tier were sufficient and more testing methods were done than required.[11]

In their reply of 28 July 2017, the Other Party explained respectively that: (i) the second legal entity is an *'exclusive toll manufacturer facility for [the Other Party]*, thus, it is regarded as an affiliate registration (ii) according to the REACH Regulation '*all available information must be used […] and considered* [redacted]*'* (iii) the tests were necessary and performed to ensure safe use of the substance by all customers.[12]

On 7 August 2017, the Claimant replied that they do not question the thoroughness of the tests carried out by the Other Party, but rather whether this thoroughness is required by REACH. They added that they were of the opinion that both companies have a different interpretation of the REACH requirements and what should be included when calculating the cost for the dossier and that they *'will let the ECHA decide'*, by filing a data sharing dispute.[13]

On 9 August 2017, the Claimant filed the dispute.

Assessment

Under Article 30 (1) of the REACH Regulation*, 'the participant (s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way'.* Registrants who need information should enter into discussions in order to agree on the nature of data they are going to share and on the cost sharing approach.

Making every effort means that the parties need to provide answers to the questions that they receive from the other party. Conversely, a party that receives a reply to their question must consider this reply. In other words, making every effort means to address questions and answers in a constructive manner to enable the parties to find a common understanding on the data that needs to be shared and the terms of sharing the data in a fair, transparent and non-discriminatory way.

At the outset, the Claimant argued that the price of the Letter of Access (LoA) was '*extremely high'* and requested a full itemisation of the study costs. Indeed, in accordance with Article 30 of the REACH Regulation and Articles 2 and 4 of the Commission Implementing Regulation[14], a potential registrant has the right to receive an itemisation of the costs related to data and administration. After having received the detailed breakdown of the study costs

[9] See the Claimant's messages dated 16/03/2017 and 21/03/2017

[10] See the Other Party's message dated 07/04/2017

[11] See the Claimant's message dated 04/07/2017

[12] See the Other Party's message dated 28/07/2017

[13] See the Claimant's message dated 07/08/2017

[14] 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]

the Claimant asked further clarification on a number of cost items. The Other Party provided the requested information and replied to the Claimant's questions in a timely manner. ECHA notes that this is in line with each parties' respective obligation to make every effort to reach a fair, transparent and non-discriminatory agreement; such information on the data and its costs is crucial for meaningful data sharing negotiations.

However, after having initially challenged the Other Party's cost calculations, the Claimant quickly concluded that they both have a different understanding of what is required for a REACH dossier and what should be included when calculating the cost for the dossier. Instead of further questioning the cost calculations and making alternative proposals, the Claimant suggested in their last reply on 7 August 2017 that they will *'let the ECHA decide'* and file a data-sharing dispute. The Claimant filed a data-sharing dispute with ECHA only two days later, without giving sufficient time to the Other Party to reply and without any other prior notice. As also indicated in the ECHA data-sharing guidance, a data-sharing dispute must be initiated *'as a last resort, i.e. only after all the possible efforts and arguments have been exhausted and the negotiations have failed'*.

ECHA observes that the negotiations were still in full progress when the Claimant launched the dispute. Both parties were actively engaged and the Claimant could have continued their efforts to come to a mutual agreement. Instead, by filing the data-sharing dispute before having given the Other Party time to react to their arguments, they brought the negotiations to a standstill. Subsequently, the Other Party was not given a fair chance to continue the negotiations and find a solution to the issues raised by the Claimant. Therefore, the submission of the data-sharing dispute was premature. As mentioned above, launching a data sharing dispute with ECHA should be done only as a last resort, i.e. only after all efforts to reach a negotiated agreement have been exhausted. By submitting a dispute before all efforts were exhausted, the Claimant failed to make every effort.

Conclusion

Based on the above, ECHA concludes that by not exhausting all efforts, the Claimant did not make every effort to reach an agreement on data sharing and access to the joint submission in a fair, transparent and non-discriminatory way, while the Other Party made every effort to find an agreement.

Annex II: ADVICE AND FURTHER OBSERVATIONS

ECHA stresses that both parties still share the common data-sharing and joint submission obligation, and are therefore still required to make every effort to reach an agreement on the sharing of the information and of their related costs. Therefore, ECHA would like to make some general observations in order to facilitate a future agreement:

- Parties of data sharing negotiations should look into different options to unblock and advance the negotiations.

- As stated by the REACH Regulation and reaffirmed by the Implementing Regulation on joint submission of data and data-sharing, registrants are only required to share the costs of information they need to fulfil their registration requirements (see Articles 27(3) and 30(1) of REACH and Article 4(1) of the Implementing Regulation). This means that registrants need to share the costs of data that relates to their information requirements, considering the tonnage band they intend to register and type of registration (standard or intermediate). This applies to both study and administrative costs (Article 4(1) of the Implementing Regulation).

[redacted]

- ECHA notes that, in case of companies with various affiliates that are separate legal entities, each of them must fulfil its registration obligations separately. Accordingly, each separate legal entity is obliged to fulfil its data and cost sharing obligations.[15]

- ECHA observes that the automatic increase of the compensation for the same data based e.g. on the argument that the existing registrants bore the expenses earlier can be discriminatory towards subsequent registrants. The existing registrants cannot unilaterally define when a registrant should have paid.

- If the future negotiations would fail, the Claimant is free to submit another claim, covering the efforts subsequent to the dispute claim that is the subject of the present decision.

Finally, ECHA reminds both parties that the outcome of a data-sharing dispute procedure can never satisfy any party in the way a voluntary agreement would. Accordingly, ECHA strongly encourages the parties to continue their efforts to reach an agreement that will be satisfactory for both parties.

[15] See ECHA's guidance on data-sharing pg. 116