[redacted]

The Claimant

[redacted]

Represented by:

[redacted]

Copy to:

[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 19 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 access to the joint submission requested from [redacted]

[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.

[redacted]

The reasons of this decision are set out in Annex I. The factual background of the dispute is described in Annex II. The instructions on how to submit your registration dossier are provided in Annex III.

b. Procedural history

On 17 November 2016, 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 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 06 December 2016.

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.

Yours sincerely,

Christel Schilliger-Musset[3]

Director of Registration

[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]

Annex I: REASONS OF THE DECISION

According to Article 19 of the REACH Regulation, all registrants of the same substance are part of the same registration under REACH ('joint submission of data'). Further, Article 3(1) 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.

Article 3(3) of the Commission Implementing Regulation also confirms that a potential registrant may decide to invoke Articles 11(3) or 19(2) of REACH in order to submit separately all or part of the relevant information in Article 10(a) of REACH. Before doing so however, the potential registrant is required to ensure that he has complied with his obligations under Articles 26 or 29 of REACH and has ascertained that he is not required to share tests on vertebrate animals for the purposes of his registration.

In such cases, Article 3(3) of the Commission Implementing Regulation requires ECHA, upon the potential registrant's request, to ensure that this separate submission of information remains part of the existing registration for the substance. It follows that in case of a failure to reach an agreement on the access to the joint submission the possibility is given to the potential registrant to submit a dispute to ECHA.

A dispute brought to ECHA in that context requires the Agency to determine whether to grant access to the joint submission. 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 made every effort to reach an agreement on the conditions for access to the joint submission.

Factual background

The Claimant initiated the data-sharing negotiations with their email of 5 July 2016 and asked for the LoA price for their registration as [redacted] *Intermediate* [redacted][4].

In their reply, the Other Party informed that the LoA cost was [redacted] but that they were currently reviewing the price[5].

The Claimant disagreed with this price and wrote that there was '*virtually no information requirement, thus no need to share data*' for their registration type. Further, they stated that they would only pay '*reasonable costs related to administration and handling the token*', and asked for an estimate of these costs.[6]

The Other Party replied that the quoted price did not cover '*test data or other non-publicly available data*' but merely expenses related to '*admin tasks, SIEF management and financial management*'. They wrote further that they also estimated future expenses, e.g. to '*maintain the registration and to cover the registration activities*[redacted], and that unused amounts would be reimbursed.[7]

The Claimant found the LoA price '*not acceptable*' and repeated that they would only pay '*a*

[4] See reference no. 1
[5] See reference no. 3
[6] See reference no. 4
[7] See reference no. 7

[redacted]

fair and transparent share of administrative costs'. They asked the Other Party to provide a '*more reasonable*' LoA price for their registration type and informed they would lodge a dispute with ECHA otherwise.[8]

The Other Party underlined again that a reimbursement of '*overestimated accounts*' would take place[9]. Further, they wrote that so far, work had been done *inter alia* related to the SIEF (SIEF communication; preparation of a SIEF agreement) as well as related to the dossier preparation, and to set up a *'LoA shop'*; for the future cost, their price estimate included dossier updates, dealing with additional co-registrants, and charges from the LoA provider. They wrote further that they had finalised the cost review and found that the costs were '*less than estimated*' previously: work done accounted to [redacted] EUR instead of [redacted] EUR, and future work to [redacted] EUR instead of [redacted] EUR. Consequently, based on two co-registrants, they recalculated a LoA price of [redacted].[10]

Following these exchanges, the Claimant indicated that they would provide feedback to the Other Party regarding the next steps[11], and proceeded to submitting the dispute on 17 November 2016.

Assessment

Based on Article 18 of REACH the information requirements for [redacted] intermediates in a tonnage band [redacted] are limite [redacted] if the substance is handled under strictly controlled conditions. This is made explicit in the Guidance on data sharing[12], which clarifies that such registrants '*are largely exempt from the obligation to submit the standard information specified in Annexes* [redacted] Therefore, it is clarified further that such registrants *'cannot be forced to share in the joint submission costs related to the data they don't need (registrants of intermediates are only required to submit any information available to them for free). Intermediate registrants might still be required to pay those administrative costs that relate to the creation and administration of the joint submission as such. However, it can be reasonably expected that these costs are rather low.'*

Additionally, as required by REACH and the Commission Implementing Regulation, registrants need to make every effort to reach a fair, transparent and non-discriminatory agreement on the sharing of data and costs. This includes among others, the right of the Claimant to receive a cost itemisation of the requested compensation for access to data and/or to the joint submission, in accordance with the requirements of Articles 2 and 4 of the Commission Implementing Regulation. Accordingly, such an itemisation needs to list cost items not only related to data (if applicable), but also related to administrative and future costs. It also needs to include justifications for each cost item.[13] This information is essential to enable a potential registrant to assess and understand the requested compensation for access to data and/or to the joint submission.

[8] See reference no. 8
[9] See reference no. 9 and 10
[10] See reference no. 10
[11] See reference no. 12
[12] See Guidance on data sharing, chapter 6.2 *Intermediates under strictly controlled conditions*, available at https://echa.europa.eu/guidance-documents/guidance-on-reach
[13] See Guidance on data sharing, chapter 5 *Cost sharing*, available at https://echa.europa.eu/guidance-documents/guidance-on-reach

[redacted]

In the case at hand, the Other Party provided information on the overall amounts of both past expenses and expected future costs that accounted for the price of the letter of access (LoA) for joining the joint submission. They also referred to a number of elements related to these costs, such as dossier preparation and submission and possible dossier updates. However, they did not break down further the overall amount of past expenses and expected future costs nor did they provide any further explanation on what those elements consisted of in particular.

Thereby, the Claimant was prevented from understanding how the overall costs had incurred and from objectively assessing the requested price. The Claimant was not able to assess whether those costs were administrative costs, which might need to be shared, or rather data related costs, which would not be required to be shared because of the limited information requirements[14].

Accordingly, the Other Party failed to comply with their obligation to make every effort to reach an agreement on the conditions to access the joint submission and the related costs in a transparent way as required by REACH and the Commission Implementing Regulation.

Further, registrants only need to share costs related to the information they are required to submit for their registration. This is in line with their obligation to make every effort to reach an agreement in a fair way.

ECHA highlights that cost items such as dossier preparation, dossier submission and dossier updates are usually not to be seen as strictly administrative costs, but rather as data related. For the registration type at hand, i.e. for [redacted] intermediates [redacted] under strictly controlled conditions, the Claimant does not need to share data but would need to compile their own registration dossier with the information available to them. Therefore, the Claimant cannot be required without further justification to share costs related to the information included in the Other Party's registration dossier. However, based on the information provided by the Other Party, and in the absence of further explanations on the elements related to these costs, it seems that the Other Party included data related expenses in their LoA offer. However, requiring the Claimant to share costs of information that is not necessary for their registration in view of their limited information requirements, does not show that the Other Party made every effort to reach an agreement on the costs for access to the joint submission that would be fair for the Claimant.

Conclusion

Based on the above, ECHA concludes that the Claimant made every effort to reach an agreement on the access to the joint submission in a fair and transparent way while the Other Party did not.

Consequently, ECHA grants the Claimant access to the joint submission for the substance subject to this dispute. This does not allow the Claimant to rely on any of the data submitted in the joint dossier.

[14] For further information on this distinction between administrative and data related costs, see Guidance on data sharing, Annex III *Cost itemisation*, available at https://echa.europa.eu/guidance-documents/guidance-on-reach

[redacted]

Annex II: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

Ref. no.	Date	Content	Remark
1.	05/07/2016	The Claimant initiates the data sharing discussions. They ask for the LoA costs and the substance identity profile, and inform that they intend to register the substance [redacted]	
2.	06/07/2016	The Other Party acknowledges receipt.	
3.	08/07/2016	The Other Party provides the substance identity profile and informs that they *'are still reviewing the current SIEF Agreement and the LoA prices'*, but that the *'guide price is* [redacted] based on two co-registrants and with reimbursements in case further companies join.	Substance identity profile not provided to ECHA
4.	13/07/2016	The Claimant writes that they *'assume there is a misunderstanding. For a REACH registration of an* [redacted] *, there is virtually no information requirement, thus no need to share data'*. With reference to ECHA's Guidance on intermediates and to the Commission Implementing Regulation on joint submission of data and data-sharing, they argue that they *'would refrain from sharing any costs related to test data or other non-pubic available data'* as the information requirement is limited to *'**existing available** data (e.g. information he holds himself or that he can obtain from other sources)'* (emphasis by the Claimant). They state they are willing to *'participate in sharing reasonable costs related to administration and handling the token'* and ask for an estimate of these costs.	
5.	29/07/2016	The Other Party writes they *'understand [the Claimant's] justification'* but still cannot provide the final LoA price. They promise to come back to the Claimant the following week.	
6.	30/07/2016	The Claimant confirms receipt.	
7.	01/08/2016	The Other Party confirms the estimated LoA price of [redacted] *'as originally stated'* and writes that	Substance

[redacted]

Ref. no.	Date	Content	Remark
		the price includes '*no test data or other non-publicly available data in the dossier therefore the price covers only admin tasks, SIEF management and financial management*'. They further inform that the amount includes '*estimated multiple hours to maintain the registration and to cover the registration activities until [redacted] REACH deadline*' and that unused amounts will be reimbursed. They also provide a revised version of the substance identity profile.	identity profile not provided to ECHA
8.	01/08/2016	The Claimant replies that '*this is not acceptable*' as they '*will only pay for data that is necessary for [their] registration and a fair and transparent share of administrative costs*'. They ask whether the Other Party is '*in the position* to *provide a price that is more reasonable for registration of an* [redacted] and inform that they will otherwise lodge a data-sharing dispute.	
9.	02/08/2016	The Other Party writes that they '*are looking at the future proofing estimates included in the LoA calculation to see if the LoA price can be reduced at this stage*' and states that any '*overestimated amount would be returned to the co-registrants anyway at the reimbursement procedure*'.	
10.	12/08/2016	The Other Party provides further information regarding the LoA price. They state that work done in [redacted] accounts for [redacted] EUR for '*SIEF communications*', '*Preparation of a SIEF Agreement*', '*Dossier preparation and submission*' and '*Setting up LoA shop*'. In addition, they estimate [redacted] in relation to '*Work for the future*', and list '*Possible dossier updates*', '*Companies joining the registration*', and '*Charges from LoA provider*' as cost items. They write that the '*LoA price was set at [redacted] euro, assuming there will be [redacted] registrants*', and state again that there will be reimbursements '*of excess charges*' and in case there are further registrants buying the LoA. The Other Party further writes that they '*have taken the opportunity to review the actual time spent to support this registration since [redacted]. These were less than estimated*'. They quote [redacted] EUR for work done, and [redacted] EUR for future costs. Consequently, they provide a new LoA price of [redacted] EUR based on [redacted] co-registrants.	
11.	30/08/2016	The Other Party asks whether the provided information '*was helpful in understanding the Letter of Access cost*' and invites to discuss '*if anything is still unclear*'.	Only provided by

[redacted]

Ref. no.	Date	Content	Remark
			the Other Party
12.	31/08/2016	The Claimant informs that the '*issue is still under discussion*' and announce they will inform the Other Party '*how the client will proceed*'.	Only provided by the Other Party
13.	02/09/2016	The Other Party acknowledges receipt	Only provided by the Other Party