[redacted]

Helsinki, 15 February 2018

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

Decision number: [redacted]
Dispute reference number:
Name of the substance:

EC number of the substance:

DECISION ON A DISPUTE

a) Decision

Based on Article 27(6) 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 27(6) 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 and the factual background in Annex II. The list of studies ECHA grants you permission to refer along with copies of (robust) study summaries can be found in Annex III and IV, respectively. Instructions on how to submit your registration dossier are provided in Annex V.

[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.

[redacted]

b) Procedural history

On 13 June 2017, you ('the Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with ('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 28 June 2017.

On 26 July 2017, ECHA requested you to provide a proof that you paid the Other Party a share of the costs incurred by them ('proof of payment'). ECHA was not informed of any agreement voluntarily reached by the parties. The proof of payment was provided on 9 February 2018 and amounted to [redacted]

a) Claim on the share of costs and Appeal of the decision

According to Article 27(6) of REACH, the Existing Registrant shall have a claim on you regarding the share of the cost, which shall be enforceable in the national courts, provided that the full study report(s) is made available to you.

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.

b) 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 on ECHA's website.[2]

Yours sincerely,

Christel Schilliger-Musset[3]

Director of Registration

[2] Available at https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach.

[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

Article 27 (2) and Article 27(3) of the REACH Regulation require existing registrants and potential registrants to make every effort to reach an agreement and to ensure that the costs of sharing the information required for registration are determined in a fair, transparent and non-discriminatory way. In this respect, the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH ('Commission Implementing Regulation')[4] established rules to ensure an efficient implementation of the data-sharing and joint submission obligations. The objective is to encourage and foster discussions among the registrants of the same substance in view of ensuring the quality of the dossier.

In case of a dispute on the sharing of studies which have already been submitted to ECHA, Article 27(6) of the REACH Regulation requires ECHA to determine whether to grant a permission to refer to the information contained in the registration dossier, i.e. to the corresponding studies, subject to the proof that the potential registrant has paid a share of the costs incurred by the previous registrant(s).

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 sharing the studies and their related costs in fair, transparent and non-discriminatory way.

Summary of factual background

The data-sharing negotiations between the parties started on 20 February 2017, when the Other Party informed the Claimant that they had been informed by ECHA that the Claimant had submitted an inquiry for the substance. Hence, the Other Party wanted to know the volume and uses for the registration with the intention to offer Only Representative (OR) coverage to the Claimant.[5]

The Claimant reacted to the Other Party's request by asking the Other Party to share with them the LoA costs for [redacted] and [redacted]. The Claimant repeated this request to obtain the LoA and data costs nine times between the end of February 2017 and middle of May 2017.[6]

The Other Party did not reply to the Claimant's requests, did not know the LoA cost and was not willing to calculate it either.[7] Instead, the Other Party proposed an arrangement for fulfilling the Claimant's registration obligations, while offering to the Claimant OR coverage on the condition that the substance is manufactured by the Other Party.[8] The Claimant consistently challenged and disagreed with the OR coverage proposed by the Other Party and also stated clearly that they were neither interested in it nor wanted it.[9]

In order to overcome the disagreements between the parties and fulfil the registration obligation, the Claimant tried to reach an agreement in different ways by asking questions

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[4] 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.

[5] See reference no. 1

[6] See reference no. 2, 4, 8, 15, 17, 20, 25, 26, and 30

[7] See reference no. 5, 12, 16, and 19

[8] See reference no. 5, 7, 10, 12, and 19

[9] See reference no. 8, 9, 11, 13, and 20

[redacted]

and proposing alternatives to progress the negotiations.[10]

Towards the end of the negotiations and after the discussion on the OR coverage had come to an end, the parties further disagreed on the provision of the Substance Identity Profile (SIP) of the substance and on who should provide the impurity profiles. Neither of the parties was willing to provide the SIP. However, with reference to their inquiry in accordance with Article 26 REACH, the Claimant argued that ECHA had indicated that their substance was the same. In addition, the Claimant requested the Other Party to indicate an acceptable '[redacted] *concentration'* regarding impurities. During the negotiations the parties could not come to an agreement on this topic.[11]

By the time the dispute was filed, i.e. 13 June 2017, the Other Party had not provided the Claimant with the requested information on the LoA and data costs.

Assessment

In accordance with Article 27 REACH and Articles 2 and 4 of the Commission Implementing Regulation, a potential registrant has the right to receive an itemisation of the costs related to data and administration as well as future costs. The existing registrants need to provide such an itemisation including proof of the cost of any study and to make every effort to provide an itemisation of all other relevant costs, including administrative costs and study costs. Finally, according to Article 2(2) of the Commission Implementing Regulation, they need to provide this information '*without undue delay*'. Such information is crucial to enable the potential registrant to assess whether the requested compensation is fair, transparent and non-discriminatory, as required by REACH and the Commission Implementing Regulation.

In the case at hand, the Claimant requested information about the LoA and data costs which they also had the right to receive. The Claimant repeated this request to obtain the data costs several times and further the Claimant also tried to reach an agreement in different ways by asking questions and proposing alternatives to progress the negotiations. Accordingly, the Claimant complied with their obligation to make every effort to reach an agreement on the conditions on data sharing and the related costs in a transparent way as required by REACH and the Commission Implementing Regulation.

On the other hand, the Other Party did not provide the requested information before the filing of the dispute. Instead, the Other Party offered Only Representative (OR) coverage, even though the Claimant was neither interested in it nor wanted it, and also stated this clearly several times.

Further, the Other Party also required the Substance Identity Profile (SIP) and the impurity profiles in order to be able to give the LoA and the data costs to the Claimant. Concerning this request, ECHA notes that the parties have to discuss about the SIP together, but this cannot, however, be used as an argument against the Claimant not to provide the requested information about the LoA and the data costs. Furthermore, the possibility to offer OR coverage and agree on the SIP and impurity levels do not matter for the obligation of the existing registrant to provide the LoA and data costs to the Claimant.

Accordingly, by taking all the above mentioned actions, the Other Party delayed the registration process of the Claimant. The Other Party did not provide the LoA and data costs and consequently did not act transparently or fulfil their obligation to provide cost itemisation '*without undue delay*' as required by the Commission Implementing Regulation. Therefore, the Other Party failed to comply with their obligation to make every effort to

[10] See reference no 6, 22, 26, and 32

[11] See reference no. 23, 24, 25, 27, 28, 29, 31 and 32

[redacted]

reach an agreement on the conditions on sharing data and the related costs in a transparent way as required by REACH and the Commission Implementing Regulation.

Conclusion

Based on the above, ECHA concludes that the Claimant made every effort to reach an agreement on data sharing in a fair, transparent and non-discriminatory way.

On the other hand, by not providing the requested cost information and by not accommodating the Claimant's request to register urgently, the Other Party breached their obligation to make every effort to reach a fair, transparent and non-discriminatory agreement.

Consequently, ECHA grants the Claimant the permission to refer to the information they requested from the Other Party.

[redacted]

Annex II: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

Ref. no.	Date	Content	Remark
1.	20/02/2017	The Other Party writes that they have been informed by ECHA that the Claimant has submitted an inquiry for the substance and asks for the volume and uses for the registration with the thought for possible Only Representative coverage.	Evidence only provided by the Other Party; Attachment not provided to ECHA
2.	24/02/2017	The Claimant asks the Other Party to share with them the LoA costs for [redacted] tpa. The Claimant also wants to know whether the '*LoA data package*' includes [redacted].	Evidence only provided by the Claimant
3.	24/02/2017	The Other Party replies that they have not calculated the LoA costs. The Other Party informs that they offer Only Representative coverage for some of their other substances and asks the Claimant to share their volume in order for the Other Party to be able to evaluate this possibility.	Evidence only provided by the Claimant
4.	24/02/2017	The Claimant repeats their request to obtain the LoA costs for [redacted].	Evidence only provided by the Claimant
5.	24/02/2017	The Other Party informs that it will require a lot of work to calculate the LoA cost. Instead, the Other Party points out that the Only Representative coverage would be for free and indicates that this option would be more beneficial for the Claimant.	Evidence only provided by the Claimant
6.	27/02/2017	The Claimant points out that they are an Only Representative and asks the Other Party to '*kindly let [them] know what [the Other Party] need in order to provide the LoA quotation*'.	Evidence only provided by the Claimant
7.	27/02/2017	The Other Party points out that as non-EU manufacturer of the substance they have appointed an	Evidence only

Ref. no.	Date	Content	Remark
		Only Representative in the EU. The Other Party further states that they can establish an agreement with the Claimant to cover their imports for free.	provided by the Claimant
8.	01/03/2017	The Claimant informs the Other Party that they disagree with the Other Party's proposal to appoint the Other Party as a new Only Representative. The Claimant repeats their request to receive the LoA costs for tonnage band [redacted] tpa. After they have received this information, they '*will decide on which tonnage level they will place an order for*'.	Evidence only provided by the Claimant
9.	08/03/2017	The Claimant states that in their opinion the proposal of the Other Party '*seems a little bit hard to comply with the REACH regulation*'. They ask the Other Party to confirm: 1. if the Other Party has submitted a [redacted] dossier or an individual REACH registration dossier. 2. if the Other Party will be commissioned as the Claimant's new Only Representative, would the Other Party submit a new registration dossier, which is completely owned by the Claimant. If this is not the case, how the Other Party plans to cover the Claimant's volume and comply with the REACH regulation.	Evidence only provided by the Claimant
10.	08/03/2017	The Other Party states that: 1. they have [redacted] dossier covering [redacted] 2. [redacted] In order to decide whether or not they can cover the Claimant's import volumes, they need to know the volume. 3. a condition to be fulfilled in order for the Other Party to provide Only Representative coverage for free is that '*the substance imported by the [the Claimant] is manufactured by [the Other Party] and no other manufacturer*'. 4. if the substance is provided by another manufacturer to the Claimant, the Claimant could consider switching to supply from the Other Party.	Evidence only provided by the Claimant
11.	10/03/2017	The Claimant indicates that the Other Party's suggestion is not a good idea because they need their own registration. The Claimant hopes that the Other Party '*can* [redacted] *give the LoA quotation or [the Other Party] can share the data cost*'.	Evidence only provided by the Claimant
12.	10/03/2017	The Other Party replies that they do not understand why the Client would '*opt for a solution that*	Evidence only

[redacted]

Ref. no.	Date	Content	Remark
		will cost them a lot of money instead of a solution that is free of charge'.	provided by the Claimant
13.	16/03/2017	The Claimant replies that '*perhaps they don't want [the Other Party] as their only supplier in the future*'.	Evidence only provided by the Claimant
14.	16/03/2017	The Other Party informs the Claimant that they have been inspected by the [redacted] Competent Authorities on their Only Representative related obligations and that they have not been challenged on their approach.	Evidence only provided by the Claimant
15.	29/03/2017	The Claimant asks the Other Party to indicate the costs of the data listed in the attachment of the email.	Attachment not provided to ECHA
16.	29/03/2017	The Other Party repeats that they have been inspected by the [redacted] Competent Authorities on their Only Representative related obligations and that they have not been challenged on their approach. The Other Party also states that they would be surprised if the Claimant prefers to pay costs for '*a probably expensive LoA over being offering OR coverage for free*'.	
17.	29/03/2017	The Claimant repeats their request to obtain the costs of the data listed in attachment of their last email.	
18.	17/04/2017	The Claimant indicates that they have called the Other Party a week ago and hence sends a kindly reminder.	Evidence only provided by the Other Party
19.	19/04/2017	The Other Party repeats again that their approach has not been challenged by the Competent Authorities. The Other Party states that it will take them '*a considerable amount of time to pay a LoA cost and that there will be additional costs for amending their dossier to be able to resubmit it as a Joint Submission dossier in IUCLID6*'.	

Ref. no.	Date	Content	Remark
		Finally, the Other Party repeats that their proposal to provide Only Representative coverage is only possible if the substance that the Claimant intends to import is manufactured by the Other Party.	
20.	21/04/2017	The Claimant states that they definitely do not accept the Other Party's offer for Only Representative coverage and as the topic has been discussed for a long time it is not necessary to continue on it. The Claimant repeats their request to obtain the costs of data listed in the attachment of their earlier email. Finally the Claimant indicates that they may need to ask for help from ECHA in case the Other Party cannot provide them the requested data costs.	
21.	21/04/2017	The Other Party asks the Claimant to explain why they do not accept the Other Party's proposal.	
22.	26/04/2017	The Claimant asks: 1. [redacted] 2. when the Claimant could join in the joint registration. 3. the Other Party to provide the LoA price for the tonnage band [redacted] so that the Claimant can first complete the joint registration [redacted] a. 4. the Other Party to provide in the meanwhile the LoA price for the tonnage bands [redacted] so that the Claimant could join in the joint registration [redacted]. The Claimant states that they consider taking the lead registrant role in case the Other Party does now allow them to join the joint registration. The Claimant requests the Other Party to estimate by 2 May 2017 when they can complete the calculation of the LoA price for tonnage band [redacted] and when the Claimant can join in the joint registration.	
23.	27/04/2017	The Other Party asks the Claimant to provide the purity level of their substance because it is '*key to know before determining the Letter of Access cost*'.	
24.	28/04/2017	The Claimant replies that they guess that the Other Party has the Substance Identity Profile (SIP) and they ask the Other Party to provide the SIP to them to be able to compare the degree of	

Ref. no.	Date	Content	Remark
		purity. The Claimant indicates that they will give feedback after the comparison.	
25.	28/04/2017	The Claimant states that the SIP comparison is the responsibility of the co-registrants and based on the comparison the co-registrants can decide whether to enter the joint submission of the substance. They further indicate that they have submitted an inquiry to ECHA which has been accepted and therefore they consider that their substance '*accords with substance standard in ECHA's view*'. The Claimant repeats the request to receive the SIP and the LoA cost.	
26.	28/04/2017	The Claimant asks the Other Party, in case it is not convenient for them to provide the SIP, just let the Claimant know the lowest concentration that the Other Party could accept according to the studies applied. The Claimant also repeats their request for LoA cost.	
27.	28/04/2017	The Other Party replies that they know that the impurity profile of this substance can affect its hazard significantly and in order to proceed they ask the Claimant to share their impurity specifications with them.	
28.	03/05/2017	The Claimant repeats their position that it is their '*responsibility to check whether the substance accords with [the Other Party's substance] and whether the impurity affect the substance hazard*'. Therefore they ask the Other Party to provide the information which impurity will affect the substance's hazard significantly. The Claimant repeats the request to receive the LoA cost for tonnage band [redacted] by 10 May 2017 or otherwise they will submit a lead registrant dossier.	
29.	03/05/2017	The Other Party replies that they will need to know the Claimant's impurities in order to include them in the SIP.	
30.	15/05/2017	The Claimant sends to the Other Party a list which contains the data that they need. They indicate that it is the same list as the one sent before. They ask the Other Party to provide the costs of the data before 29 May 2017.	Attachment not provided to ECHA
31.	15/05/2017	The Other Party replies that the data listed in the Claimant's attachment seems to differ from the	

Ref. no.	Date	Content	Remark
		data that the Claimant needs as per ECHA's communication but also from the Claimant's earlier request for costs linked to the tonnage band[redacted]. With reference to ECHA guidance on data sharing the Other Party states that the impurity profile of the Claimant's substance may affect its properties and therefore the parties need to agree on what data is relevant to the Claimant's substance.	
32.	17/05/2017	The Claimant states that the data list is the same as the one provided before and that the list is based on the inquiry report received from ECHA. If the Other Party is not the data holder for some of the data or if they do not agree with the inquiry result, the Claimant asks the Other Party to '*specify the involved endpoints or provide [to the Claimant] the data endpoints which [the Other Party] could share for* [redacted] *registration*'. Furthermore, the Claimant states that: 1. in accordance with the inquiry report issued by ECHA, the Claimant's substance is consistent with the Other Party's substance. This means that the impurity profile of the Claimant's substance will not affect the data sharing of the substance. Hence, the Claimant's substance information is in conformity with that of the Other Party. 2. it is the obligation of the lead registrant to provide a proposed SIP to the potential co-registrants for discussion. 3. ECHA guidance indicates that communication between potential and existing registrants may result in adaptation of the SIP. So far the Claimant has not received any proposed SID. 4. if the Other Party wants to be the lead registrant, they should provide a SIP for comparison. The liability concerning whether the identity is applicable should be on a potential co-registrant. 5. ECHA guidance on data sharing does not require a co-registrant to provide the lead registrant with the purity and impurity profile of the substance. The Claimant continues by stating that to some extent they think that the Other Party is '*deliberately to stall for time and hinder [the Claimant] from successfully completing their registration*'. Finally, the Claimant requests to receive by May 19 2017 the cost of the data listed in the attachment of their earlier email or inform them if the Other Party do not want to sell the data access to them.	
33.	27/05/2017	The Claimant states that they have not received any reply to their email of 17 May 2017. They	

Ref. no.	Date	Content	Remark
		further state that if they do not receive the reply by 31 May 2017, they will file a dispute to ECHA.	