29 June 2016

Addressee (Claimant):

Sent via REACH-IT

Copy to Other Party:

Sent via REACH-IT

Reference number of the dispute claim	
Decision number	
Name of the substance disputed	
EC number of the substance disputed	[1]

DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 30(3) OF THE REACH REGULATION (EC) No 1907/2006

Dear ,

On 5 April 2016, , represented during the data sharing negotiations by (hereinafter referred to as 'the Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with (hereinafter referred to as 'the Other Party'), as well as the related documentary evidence to the European Chemicals Agency (ECHA). The claim has been registered at ECHA on 5 April 2016.

To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA requested the Other Party to also provide documentary evidence regarding the negotiations. The Other Party submitted the documentary evidence on 21 April 2016, as requested by ECHA.

[1] When submitting the data sharing dispute claim, the Claimant indicated the substance with EC no. on the webform. However, the documentary evidence provided by both parties unambiguously indicates that the parties agreed to negotiate data sharing for the substance with EC no. . To reflect the actual subject of the data sharing negotiations, ECHA has therefore adapted the scope of the data sharing dispute accordingly.

Based on the documentation supplied by both parties, ECHA has decided to grant you, as the Claimant, the permission to refer to the vertebrate animal studies requested from the Other Party for the above-mentioned substance.

The Other Party shall have a claim on you for an equal share of the cost, provided they make the full study report available to you, which shall be enforceable in the national courts according to Article 30(3) of REACH.

In accordance with Article 3(2) of the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data sharing[2], ECHA also provides you with the token to the joint submission in order to ensure that your registration dossier will be part of the existing joint submission for the substance.

The permission to refer concerns the studies indicated in Annex I. The statement of reasons regarding the assessment of the data sharing dispute is set out in Annex II to this decision while a tabular overview of the factual background regarding the data sharing negotiations is set out in Annex III. Instructions on how to prepare and submit your registration dossier after the resolution of the data sharing dispute procedure are provided in Annex IV. The endpoint study records for which permission to refer has been granted for the substance are provided in Annex V.

As a remark, ECHA reminds both parties that despite of the present decision they are still at liberty to reach a voluntary agreement. This would be in the parties' own interest, because they could enter into an agreement that reflects their needs, including, in particular, the sharing of non-vertebrate animal data, which is not covered by the permission to refer granted in the present decision. Accordingly, ECHA strongly encourages the parties to negotiate further in order to reach an agreement that will be satisfactory for both parties.

In accordance with Article 30(5) of the REACH Regulation, both parties involved in the dispute may appeal against this decision to the Board of Appeal of ECHA within three months of the notification of this decision. The procedure for lodging an appeal is described at http://echa.europa.eu/web/guest/regulations/appeals.

Yours sincerely,

Christel Schilliger-Musset
Director of Registration

Annexes:
Annex I: List of studies subject to the dispute, to which ECHA grants the permission to refer
Annex II: Statement of reasons regarding the assessment of the data sharing dispute
Annex III: Factual background regarding the data sharing negotiations
Annex IV: Instructions on how to prepare and submit your registration dossier after the resolution of the data sharing dispute procedure
Annex V: Endpoint study records for which permission to refer has been granted for the substance

[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.

Annex I to decision [redacted]

LIST OF STUDIES SUBJECT TO THE DISPUTE, TO WHICH ECHA GRANTS THE PERMISSION TO REFER

Below ECHA has listed the studies involving vertebrate animal testing for which the Claimant has been granted a permission to refer. Studies that were subject to the negotiations but do not involve vertebrate animal testing are not covered by the permission to refer granted in this decision.

Endpoint	Title of the study
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Annex II to decision [redacted]

STATEMENT OF REASONS REGARDING THE ASSESSMENT OF THE DATA SHARING DISPUTE

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, so as 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.

Making every effort to share the data and their related costs in a fair, transparent and non-discriminatory way means that the parties negotiate the sharing of data and related costs as constructively as possible, to make sure that the negotiations move forward swiftly by expressing their arguments and concerns and replying to each other's questions and arguments. Where a party promises to provide an agreement on data sharing and/or joint submission, keeping their promise and being reliable and consistent is part of making every effort. When they see that the claimant needs the agreement urgently, they must take this into account, and not delay sending such an agreement to the claimant.

Existing registrants are also required to provide to potential registrants upon request the itemisation and justification of all relevant costs to be shared, both data-related and administrative costs. This information will help the potential registrant to understand the data owner's cost calculation and thus allow them to enter into meaningful data sharing negotiations.

Factual background

The Claimant initiated the negotiations with an email dated 2 October 2014 expressing their interest in registering 'an UVCB substance, using data in Read across from [redacted] already registered substances EC [redacted] and [redacted]'.[3] In the following the parties agreed to negotiate data sharing for the substance with EC number [redacted].[4]

On 6 February 2015 the Claimant confirmed their interest in buying a Letter of Access (LoA) for the substance in question and asked for additional information about the process of buying the LoA and the costs for the different tonnage bands.[5] The Other Party provided the price for the LoA for [redacted] tones on 14 April 2015. [6] On the same day, the Claimant replied that

[3] See document Ref. no.1
[4] See document Ref. no. 3, 4, 5
[5] See document Ref. no. 8
[6] See document Ref. no. 11

they 'asked for every tonnage band' and requested specifically the costs for [redacted] tones.[7] On 15 July 2015 the Other Party replied that in the beginning of August they will send them 'the SIEF agreement first, and when signed, (…) the invoice'. [8] In the following months, the Claimant repeatedly asked for the costs for the LoA for [redacted] tonnes and for the SIEF agreement[9], and on 23 October 2015, when the Other Party had provided neither, mentioned the possibility of launching a dispute.[10]

On 29 October 2015, the Other Party provided the price of LoA for [redacted] tonnes and promised to issue a SIEF agreement if the Claimant was 'interested to pursue'.[11] In response, the Claimant confirmed their interest in the LoA and asked the other party to 'indicate in detail the costs (proof of costs) for each study and the administrative calculation for a fair and transparent sharing'.[12]

On 6 November 2015 the Other Party specified the overall costs for the [redacted] tonnage band and distinguished the sum of the toxicological and ecotoxicological tests from the sum of the physical-chemical tests, but did not provide a study by study cost breakdown.[13] The study by study breakdown was not provided by the time the dispute was filed.

On 7 December 2015 the Claimant stated their interest in the [redacted] tonnes SIEF agreement and provided the legal entity name to be included in the agreement.[14] On 14 December 2015, the Other Party replied that the SIEF agreement was under review by their legal department and would be provided soon.

On 27 January 2016, the Claimant asked whether uses could be added. The Other Party informed that this would need to be done by the Claimant themselves[15]. The discussion on access to the necessary information to develop the additional uses was not concluded by the moment the dispute was launched.[16]

On 18 March 2016, the Claimant wrote to the Other Party that they needed to register soon, and that the request was urgent. On the same day, the Other Party informed the Claimant that they had hired an external consultant to support the SIEF and LoA management, and that the consultant would revert to the Claimant. The consultant took contact with the Claimant on 24 March 2016, writing that they would need time and further discussions, before they could grant access to the joint submission and asked for patience.

The SIEF agreement was not provided by the time the dispute was launched.

[7] See document Ref. no.12
[8] See document Ref. no. 14
[9] See document Ref.no.18, 19,20,21, 23, 24, 25
[10] See document Ref.no. 25
[11] See document Ref.no. 27
[12] See document Ref.no 28
[13] See document Ref.no. 29
[14] See document Ref.no. 31
[15] See document Ref. no. 40
[16] See document Ref.no. 35,40

Assessment

While the Claimant referred to the substance with list number [redacted] in the claim, it follows from the evidence they submitted as well as the evidence submitted by the Other Party that they meant the substance 'Reaction product of [redacted]' (EC number [redacted]). Both parties submitted evidence pertaining to the same negotiations, in which the parties quickly agreed on the substance sameness and the substance to which the Claimant wanted to buy a LoA[17].

The Other Party had promised to send a SIEF Agreement for the first time on 15 July 2015. They repeated their intention to provide them with a SIEF Agreement on 18 September 2015, 29 October 2015, 6 November 2015 and 14 December 2015. The Claimant asked for the SIEF Agreement on 11 September 2015 and again stated their interest on 18 September 2015, 23 October 2015, 2 November 2015, 16 November 2015, 7 December 2015, 14 December 2015 and 12 January 2016.

Thus, the Other Party had committed to providing the Claimant with a SIEF Agreement, i.e., an agreement on data sharing and joint submission. The Claimant was interested and requested the SIEF Agreement as a matter of urgency. The SIEF Agreement was however never provided by the Other Party.

There is no fixed timeline, within which a party must provide a SIEF Agreement. Whether the provision of the SIEF Agreement was a matter of urgency depends on the overall negotiations and their context. The Claimant showed an interest mainly in the [redacted] tonnes band during most of 2015, because they repeatedly asked for the price of the data at that tonnage band. Although the Claimant stated that it was urgent, their requests for the [redacted] tonnes band indicated that there was no real urgency, because they would not need to register at [redacted] tonnes until 2018.

Further, it must be taken into account that the Other Party was the only existing registrant of the substance, and thus may not have had a ready SIEF Agreement when they were first contacted by the Claimant. It should also be taken into account that any SIEF Agreement that they may have prepared during 2015 could have been for the [redacted] tonnes band. Finally, the Implementing Regulation contained explicit requirements for the contents of a SIEF Agreement, and information on the provisions had become public during autumn 2015.

However, the Claimant explicitly asked for the SIEF Agreement for the [redacted] tonnes band on 7 December 2015. At this point in time, the urgency must have become clear to the Other Party, too. The registration deadline for the [redacted] tonnes band had expired in 2013. Moreover, the Other Party knew that the negotiations had been extending over more than a year in December 2015; the Claimant had said that the negotiations were urgent already on 6 February 2015 and repeated it since then.[18] On their side, the Other Party had repeatedly confirmed since July that they were going to send a SIEF Agreement. Finally, on 14 December 2015, they created the impression that the SIEF Agreement was almost ready and only needed a legal review, so that it would be provided 'soon'. However, they only involved a

[17] See document Ref.no. 1,4,5

consultant from March 2016, who announced that further time was going to be needed and asked for patience.

Considering the message that the SIEF Agreement would be provided soon, the overall duration of the negotiations and the apparent urgency on the side of the Claimant, the Other Party's silence until 18 March 2016 and the following message that a consultant would do the work and further time is needed could not amount to making every effort to find an agreement.

On 27 January 2016, the Claimant asked if additional uses could be added[19]. Only on 18 March 2016 the Other Party informed the Claimant that the 'additional uses will not be incorporated in the lead dossier'. This request to add possible additional uses does not justify the delay to provide the SIEF agreement.

Further, the Claimant has the right to receive upon request detailed information regarding the costs of the LoA, i.e., a study-by-study cost breakdown, as this information is necessary to allow a thorough understanding of the underlying cost calculation, to negotiate data and their cost and to assess whether the cost sharing is fair, transparent and non-discriminatory as required under REACH. The Claimant's right to such information has been further substantiated with the Implementing Regulation on joint submission of data and data sharing[20] which sets out criteria for the itemisation of data and costs to be provided upon request. Also by not providing the study by study cost breakdown despite repeated requests over a period of several months, the Other Party did not make every effort to find an agreement on data sharing.

Conclusion

Based on the above, ECHA concludes that the Other Party did not make every effort to reach an agreement to share data. In particular, in a situation where it was clear that the Claimant needed to share data urgently, the Other Party did not provide the SIEF agreement that they had promised and of which they had the created the impression that it would be sent soon. This resulted in a failure to reach an agreement on the sharing of data and their costs as required by Article 30 REACH.

Therefore, ECHA grants the Claimant permission to refer to certain data, submitted by the Other Party, listed in Annex I to the present decision.

[19] See document Ref.no. 35
[20] See document Ref.no. 1,4,5

[redacted]

Annex III to decision [redacted]

TABULAR OVERVIEW OF THE FACTUAL BACKGROUND REGARDING THE DATA SHARING NEGOTIATIONS

Ref. No.	Date	Content	Remark
1	02/10/2014	The Claimant contacts the Other Party for first time. The Claimant informs that they intend to register 'an UVCB substance, using data in Read across from [the Other Party's] already registered substances EC [redacted] [and] [redacted]' and asks 'if [the Other Party] is willing to share the related studies, under an agreement'.	
2	02/10/2014	The Other Party replies and informs that they 'need some time' to work on the request.	
3	23/10/2014	The Other Party contacts the Claimant and asks 'to know the name and the CAS number of the substance for which your customer think he can use read across'.	
4	23/10/2014	The Claimant informs that the substance which needs to be registered is EC [redacted] / CAS [redacted]. The Claimant repeats their request to share data from the Other Party for the following two dossiers: [redacted] and [redacted].	
5	17/11/2014	The Other Party confirms that the mentioned CAS number 'is in fact included in our Reach registered substance EC[redacted]' due to the need to rename the substance for REACH. Therefore, they propose the Claimant to buy LoA and promise to send all the needed information.	
6	15/01/2015	The Claimant apologies for the delay and informs that @the analytical characterization is ongoing'. The Claimant requests additional information about the LoA and the SIEF agreement.	
7	28/01/2015	The Other Party provides the SIP for the substance in question and asks the Claimant to inform them if they 'are still interested in registering the substance'.	
8	06/02/2015	The Claimant informs that they are interested to register the substance. They ask for the LoA, the costs for the different tonnage bands and the 'modality' of buying the LoA. The Claimant informs that 'it is	

Ref. No.	Date	Content	Remark
		urgent'.	
9	06/02/2015	The Other Party confirms that the request has been taken into account and that they are 'currently preparing the LoA cost and the documentation'.	
10	05/03/2015	The Claimant asks if there are 'news regarding the LoA' and requests information about the cost so that their client 'can start to think about the budget'.	
11	14/04/2015	The Other Party informs that the price for the LoA for [redacted] t is [redacted] euro and informs about their contact person from now on.	
12	14/04/2015	The Claimant explains that they 'asked for every tonnage band' and requests the costs specifically for [redacted]/y	
13	09/07/2015	The Claimant renews their requests and asks 'how to proceed for the request of the mentioned letter of access'.	
14	15/07/2015	The Other Party informs that they will contact them in the beginning of August and they will send them 'the SIEF agreement first, and when signed, […] the invoice'.	
15	17/07/2015	The Claimant informs that they will wait for the SIEF agreement.	
16	31/07/2015	The Other Party asks if the Claimant wants to join both SIEFs for EC[redacted] and [redacted]. They enclose both SIPs and the SIEF agreement for the isopranol substance, which has already been signed with another co-registrant.	
17	10/08/2015	The Other Party informs that the contact person has changed	
18	24/08/2015	The Claimant informs about a change in contact person. They confirm that they 'would like to join the joint registration for the butanol reaction product only (EC # [redacted])', and ask for the SIEF agreement.	

[redacted]

Ref. No.	Date	Content	Remark
19	31/08/2015	In addition to their previous request, the Claimant asks for the costs for a LoA for [redacted] t.	
20	11/09/2015	The Claimant repeats their request for the SIEF agreement for EC [redacted] and the costs of the LoA for [redacted]. They further ask if the CSR is included in the costs and request '[a]n outline of other costs involved: e.g. administrative costs etc'. The Claimant informs that the request is urgent.	
21	18/09/2015	The Claimant renews their request of 11 September 2015.	Provided only by the other party
22	18/09/2015	The Other Party answers that they will update the documents '[i]n the coming weeks' but that they 'need more time to do the work'.	Provided only by the other party
23	30/09/2015	The Claimant requests a reply on his questions of 11 September 2015.	
24	23/10/2015	The Claimant resends his questions from 11/09/2015	
25	23/10/2015	The Claimant quotes Article 30 REACH and highlights the deadlines and the possibilities offered by the dispute procedure. They underline that they have been requesting a LoA since October 2014 and that '[d]uring the last 6 months [the other party] continuously postponed the answer without clear reasons'. Finally, they inform that they will contact ECHA to ask 'to register without the data' if the other party doesn't 'react properly according to what the Regulation requires'.	
26	23/10/2015	The Other Party apologizes for the delay and promises to provide the claimant with the requested information '[n]ext week'.	
27	29/10/2015	The Other Party provides the SIP for the requested substance and informs that the price for the LoA for [redacted] is [redacted] euro. The price includes advantage compensation [redacted] euro, SIEF management [redacted], and CSR [redacted]. They further inform that they will issue a SIEF agreement if the Claimant is 'interested to pursue'.	

[redacted]

Ref. No.	Date	Content	Remark
28	02/11/2015	The Claimant informs that they 'already received and accepted the SIP' and that they have been waiting to receive the SIEF agreement. Additionally they ask if the Other Party intends to 'update [their] dossier in a Joint submission releasing a token' and which tonnage band will be covered by the dossier. Finally, given that the Other Party had quoted a different LoA price earlier, they ask to 'indicate in detail the costs (proof of costs) for each study and the administrative calculation for a fair and transparent sharing'.	
29	06/11/2015	The Other Party confirms that their dossier is [redacted] individual and that they 'intend to update our dossier in a Joint submission releasing a token'. The price for the LoA is explained further: [redacted] (Annex [redacted]); [redacted] (Annex [redacted]). They provide additional information for the [redacted] dossier: toxicological and ecotoxicological tests [redacted]; and physico-chemical tests [redacted], Therefore, the 'costs of the technical dossier Annex [redacted]' is [redacted]. The Other Party informs that they are finalising the SIEF agreement and will 'provide it […] shortly'.	
30	16/11/2015	The Claimant looks forward to the SIEF agreement and underlines they 'expect that it will be in line with incoming Regulation, indicating therefore the compensation rules'. They further inform that 'this registration will be postponed to the next year'.	Provided only by the other party
31	07/12/2015	The Claimant asks for the SIEF agreement for [redacted] and provides the legal entity name to be included in the agreement. They further ask to receive the SIEF agreement 'before the Christmas break'.	
32	14/12/2015	The Claimant resends their email from 07/12/2015	
33	14/12/2015	The Other Party informs that the SIEF agreement is under review by the legal department and that they will provide it 'soon'.	
34	12/01/2016	The Claimant repeats their request of 14 December 2015.	Provided only by

[redacted]

Ref. No.	Date	Content	Remark
			the other party
35	27/01/2016	The Claimant asks if it is possible 'to add uses in the registrations' and asks if the LoA costs would be influenced.	
36	03/02/2016	The Claimant sends a list of uses and asks again 'if and how the LoA cost will be influenced'.	
37	16/03/2016	The claimant repeats their request of 27/01/2016.	
38	18/03/2016	The Claimant informs that their 'client needs to register as soon as possible' and that 'it is an urgent request'.	
39	18/03/2016	The Other Party informs that they have hired an external consultant to 'support the SIEF and LoA management' and that the consultant will 'revert to [the Claimant] to complete the sale of data and provide the requested information'.	
40	24/03/2016	The external consultant representing the Other Party informs that 'reviewing the required information to progress with the sale of a LoA to provide your client with access to the JSO etc. so that they may proceed with registration. There will be some further discussions needed […] before finalisation, so thank you for your continued patience.' In addition, they inform that the additional uses will not be incorporated in the lead dossier and therefore 'the additional uses need to be developed' for the claimant.	
41	31/03/2016	To add the uses and to update the CSR, the Claimant asks 'for every endpoints, the representative values, already used for the PNEC and DNEL calculations'. They further inform that the registration is urgent and underline that they have been requesting the LoA and the additional uses for 'several months' already.	
42	31/03/2016	The Other Party provides links to ECHA dissemination webpage with information about DNELs and PNECs.	

[redacted]

Ref. No.	Date	Content	Remark
43	01/04/2016	The Claimant explains that 'to make complete assessment [we] need […] also the summaries of each end point (especially physical-chemical and environmental fate)'.	
44	18/04/2016	The Other Party informs that 'a pdf file from the iuclid doc' will be send the following day	Provided only by the other party
45	Undated (after 01/04/2016)	The Other Party sends 'the IUCLID file containing the information required to develop the uses'	Provided only by the other party; attachment (IUCLID file) not provided to ECHA
46	19/04/2016	The Claimant reminds that they 'are waiting for the SIEF agreement to permit to the client to obtain the token and register as soon as possible', underlining that '[t]his is more important than the IUCLID file'. They further remind that they wait for the cost details for [redacted].	Provided only by the other party