[redacted]

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 Article 11 and 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].

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

b) Procedural history

On 28 November 2016, you ('the Claimant') submitted a claim concerning the failure to reach an 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

[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]

Other Party submitted the documentary evidence on 2 January 2017.

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 11 and 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 assesses 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 11 May 2016[4] and expressed an interest to register [redacted] ('the substance') as an [redacted] intermediate (under strictly controlled conditions). The Other Party communicated the price of the letter of access (LoA) for [redacted] tpa stating that this *'includes the LOA for intermediate registration'.*[5]

The Claimant further requested the cost breakdown of the requested costs for the LoA regarding the substance as well as [redacted] other substances.[6] The Other Party provided the LoA costs for [redacted] tpa and [redacted] tpa for the requested substances without, however, providing the requested cost breakdown. The Other Party also asked the Claimant to specify whether they were interested in registering those substances so that the Other Party could send *'further details for joining the joint registration'.*[7]

The Claimant confirmed their interest to register those substances. They pointed out that *'[r]egistrants are only required to share the costs of information they need to submit'* and repeated their request to receive the cost breakdown of the LoA for the substance as well as the other discussed substances.[8]

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

[redacted]

Following, on 6 October 2016, after four months without having received a reply from the Other Party to the Claimant's aforementioned request for a cost breakdown, the Claimant informed all SIEF members of the substance about their interest in creating a joint submission for the substance for intermediate use. The Claimant also asked the SIEF members to indicate, before 16th October 2016, whether they were interested in joining that joint submission and undertaking the lead registrant's role.[9] The Claimant pointed out that, in case they would receive no reply by the set deadline, they would consider as having received themselves the other (potential) registrants' consent to act as the lead registrant for that joint submission.

On the same date, i.e. 6 October 2016, reacting to the Claimant's aforementioned email, the Other Party sent an email to the SIEF members indicating that the joint submission for which they acted as lead registrant covered the intermediate use of the substance. The Other Party also stated that *'as per one substance one registration principle (OSOR) of the REACH regulation two joint submissions are not allowed for the same substance'*.[10] In addition, the Other Party requested the Claimant *'to immediately withdraw [their] SIEF survey otherwise [the Other Party] will contact the authorities for […] this second joint registration for the same substance'* and added that *'[y]ou are […] free to contact us in case you want to register the substance.'* [11]

On 14 October 2016, the Claimant replied that, based on REACH and its implementation in REACH-IT, they are allowed to create two separate joint submissions covering the standard and intermediate use of a substance respectively. They pointed out that it *'is up to the companies intended to register as intermediate use only under SCC [strictly controlled conditions] to create an intermediate JS[…] together or joining available full registration'*.[12] The Claimant expressed however their openness to continue discussions with the Other Party in order to still explore the possibility of joining the joint registration for both standard and intermediate use of the substance, for which the Other Party acted as lead registrant.

On 25 October 2016, in the absence of a reply from the Other Party to their last email, the Claimant repeated again their previous request for a cost itemisation of the LoA regarding the substance and three other substances. The Claimant set a deadline of 27 October 2016 to the Other Party for providing this information, informing them that they would otherwise proceed with creating a separate joint submission for the substance for intermediate use, as previously indicated.[13]

On the same day, i.e. 25 October 2016, the Other Party sent to the Claimant the requested cost breakdown of the LoA costs for joining the joint submission as member registrant for intermediate use regarding one of the five discussed substances.[14] The Claimant replied that *'[a]t first [they] could agree with the cost [the Other Party] indicate[d]'* and asked for some further information regarding the reimbursement mechanism, administrative costs and classification of the substances as well as the bank account details of the Other Party in order to proceed with the payment of the requested costs.[15] The Other Party confirmed that the same costs apply for all discussed substances[16] and provided[17] the requested information.

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[9] See reference no. 8
[10] See reference no. 9
[11] *Ibid.*
[12] See reference no. 10
[13] See reference no. 12
[14] See reference no. 13
[15] See reference no. 14
[16] See reference no. 18
[17] See references no. 15 & 20.

[redacted]

They also promised to send a copy of the SIEF agreement for the substance.[18] On 7 November 2016, the Claimant informed the Other Party that they initiated the payment of the requested costs and asked the Other Party for the provision of the token to allow them to join the existing joint submission.[19]

On 15 November 2016, the Claimant sent an email to the Other Party pointing out that they had realised that in the meantime the Other Party had created a separate joint submission for the intermediate use of the substance without informing the other members of the SIEF. The Claimant reminded the Other Party that when the Claimant had enquired the SIEF members for the creation of a separate joint submission for intermediate use, the Other Party had not expressed their interest in it. The Claimant noted that they considered the Other Party's action '*illegal as [the Other Party] do[es] not comply with REACH regulations in what refers to SIEF formation, LR [lead registrant] nomination and data sharing*'.[20] They thus requested the Other Party to '*regret in [their] procedure and solve this situation*' and indicated that '*[o]therwise I [the Claimant] would be force[d] to initiate an appellation against [the Other Party]*'.[21]

On the following day, i.e. 16 November 2016, the Other Party sent to the Claimant the SIEF agreement.[22] They did not however comment on the Claimant's aforementioned last email. Eventually the Claimant submitted the dispute on 28 November 2016.

Assessment

Articles 11 and 19 of REACH, as further implemented by the Commission Implementing Regulation on joint submission of data and data sharing, impose the obligation for potential registrants of the same substance to jointly submit data.

As ECHA's Guidance on data sharing also explains,[23] registrants of the same substance are required to register jointly regardless of the use, i.e. intermediate and non-intermediate. However, due to the reduced information requirements applicable to intermediates [redacted] tpa used under strictly controlled conditions, registrants of intermediates may choose for practical reasons to, either form a joint submission together with the registrants registering the substance for standard use; or, to form one parallel joint submission for intermediate use only. In practical terms, it is desirable to have one single joint submission covering both intermediate and non-intermediate use. However, for example, in a situation that may otherwise lead the registrant to open a dispute via ECHA, he may opt for a separate joint submission.

Further, making every effort to find an agreement on the sharing of data and the conditions for access to the joint submission requires potential and existing registrants to be a reliable partner in the negotiations. Parties are thus required to be consistent and transparent in their discussions and must not undermine the progress of the negotiations by resorting to unilateral actions that go against the parties' previous discussions, declared interests or agreements.

Based on the negotiations, the Claimant contacted the Other Party expressing their interest to register the intermediate use of the substance as part of the joint submission for which the Other Party acted as lead registrant. Having received no reply to their repeated request for a

[18] See reference 20
[19] See reference no. 21
[20] See reference no. 22
[21] *Ibid.*
[22] See reference no. 23
[23] See section 6.2. 'Intermediates under strictly controlled conditions', on page 154.

cost breakdown of the LoA costs for joining the joint submission, the Claimant indicated to the SIEF members their interest to create a separate joint submission for the intermediate use of the substance and act as its lead registrant. The Other Party, however, strongly opposed the creation of a separate joint submission by the Claimant stating that they would report the Claimant's action to the relevant authorities as breach of the REACH joint registration requirements. Following that, the Claimant agreed to continue discussions with the Other Party on joining the joint submission for the substance for which the Other Party acted as lead registrant. After receiving the requested cost breakdown as well as further information on the conditions for access to the joint submission, the Claimant expressed their agreement with the requested costs and proceeded with the initiation of the respective payment to the Other Party. In the meantime, however, the Other Party created a separate joint submission for the intermediate use of the substance against their previous strong opposition to such action intended to be carried out by the Claimant.

ECHA notes that the creation of that separate joint submission for the intermediate use of the substance by the Other Party did not show consistency and reliability on their side as a negotiating partner and effectively undermined the parties' negotiations. The Other Party had previously strongly opposed the Claimant's expressed interest in creating a separate joint submission for intermediate use for the substance. The Other Party claimed that a separate joint submission for intermediate use next to the existing one for which they acted as lead registrant would be in breach of the REACH joint registration requirements. They also stated that if the Claimant proceeded with the creation of a separate joint submission for the substance they would have reported that action to the relevant authorities. Following the Other Party's reaction to their declared intentions, the Claimant then agreed to continue the parties' previous negotiations regarding the Claimant's access to the joint submission for standard and intermediate use for which the Other Party acted as lead registrant.

In addition, before proceeding with creating a separate joint submission for the intermediate use of the substance, the Other Party had not informed the Claimant thereof. This, however, prevented the parties from the opportunity to discuss whether the Claimant would still be interested in creating themselves a separate joint submission for the intermediate use of the substance, discuss the options available and their respective impact on the ongoing negotiations between the parties.

Based on the above, ECHA concludes that the Claimant made every effort to reach an agreement with the Other Party 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 covering the standard and intermediate use of the substance that is subject to this dispute. This does not allow the Claimant to rely on any of the data submitted in the joint submission dossier.

Additional Remarks

The present decision concerns the Claimant's access to the joint submission covering the standard and intermediate use of the substance. Should the Claimant be interested in the joint submission for intermediate use, which was created by the Other Party during the parties' negotiations, ECHA notes the following:

As a result of the Commission Implementing Regulation on data sharing and joint submission, ECHA has set up a specific mechanism to address disputes regarding the legitimacy of lead registrants separately from data sharing disputes and/or disputes concerning access to the joint submission. If the Claimant wishes to challenge the legitimacy of the lead registrant concerning the separate joint submission for intermediate use, they can request ECHA to take action. On this basis, ECHA can contact the other (potential) registrants for the substance to

[redacted]

seek information on the appointment of the lead registrant. If the information received confirms the concerns expressed by the Claimant, the Agency shall ensure that the lead registrant role is undertaken by the legitimately appointed lead registrant. This however shall be without prejudice to the data already submitted.

[redacted]

Annex II: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties[24]:

CHRONOLOGY TABLE		
Reference number	**Submission date**	**Article**
[redacted]	28/11/2016	30(3)

Ref. no.	Date	Content	Remark
1.	11/05/2016	The Claimant initiates negotiations with the Other Party for the substance [redacted] and expresses an interest to register it as an isolated intermediate. The Claimant also asks the Other Party to '*create a joint submission in order to provide [the Claimant] the security token*'. The Claimant further informs that they have no relevant data about the substance but as far as they know they do not need '*any kind of extra data for [their] registration dossier*'.	
2.	11/05/2016	The Other Party asks the Claimant to provide substance sameness information for [redacted]. The Other Party also requests the Claimant to fill in a Joint Registration Form. They further inform that the related two documents have '*no specific binding on timing of registration or registration itself*'. The Other Party then states that these documents will enable them to send '*the requested letter of access cost*' to the Claimant. In addition the Other Party informs that '*actual payment procedure will only be involved*' after the Claimant finalises '*intention to register a substance*'. The Other Party also explains that the following steps will be SIEF agreement and invoicing.	Attachments not provided

[24] Only the negotiations that relate to the disputed substance are included.

[redacted]

Ref. no.	Date	Content	Remark
		The Other Party further writes that letter of access cost may be regularly reviewed based on '*various factors*'.	
3.	12/05/2016	The Claimant returns a filled Joint Registration Form to the Other Party.	Attachments not provided
4.	12/05/2016	The Other Party informs that '*the lump sum letter of access*' for [redacted] is [redacted] € '*which includes the LOA for intermediate registration*'. The Other Party further lists that the letter of access includes sections [redacted]. The Other Party also states that the letter of access contains '*Chemical safety assessment and Chemical safety report (Except for registrations as Intermediates and less than* [redacted]'. The Other Party then asks the Claimant to '*confirm the LOA along with the tonnage band of [their] interest*' so that the Other Party can send the Claimant '*the SIEF agreement including cost break up based on the JSF information*'. The Other Party further informs that '*the costs are valid till September[…] 2016*'.	
5.	15/06/2016	The Claimant asks the Other Party to send '*individual cost*' of [redacted] and three other substances '*ASAP, [the Claimant] would like to start with the registration before August*'.	
6.	16/06/2016	The Other Party informs the Claimant that the name and CAS numbers mentioned in the Claimant's email of 15 June 2016 do not match and lists the correct names and CAS numbers. The Other Party further gives [redacted] Letter of Access cost for [redacted]: [redacted] and repeats the cost for [redacted]: [redacted]. The Other Party then asks the Claimant whether they are interested in registering [redacted] so that the Other Party can send '*further details for joining the joint registration*'.	
7.	20/06/2016	The Claimant apologises for mistake with CAS numbers and points out that the Claimant '*have already sign[ed] the JSM for those substance[s]*'.	

[redacted]

Ref. no.	Date	Content	Remark
		The Claimant stresses that as ECHA advises '*[r]egistrants are only required to share the costs of information they need to submit*'. The Claimant further asks for '*cost of each item […] indicating the cost of individual studies, administrative costs, etc.*'	
8.	06/10/2016	The Claimant informs the Other Party and other [redacted] SIEF members of interest '*to initiate the process in the SIEF to register the substance* [redacted] *as an intermediate under SCC*'. The Claimant further states that '*[t]here is already a FULL JS for this substance where [Other Party] is the LR*'. The Claimant also asks whether the SIEF members are interested in joining in the Intermediate Joint Submission and if they '*are interested in being LR before 16th October 2016*'.	
9.	06/10/2016	The Other Party emails the Claimant with the SIEF members in copy. The Other Party states that they have '*registered the substance with full use during* [redacted] *deadline this also covers the intermediate use of the substance and thus we object your […] survey*' and that '*as per one substance one registration principle (OSOR) of the REACH regulation two joint submissions are not allowed for the same substance*'. The Other Party requests the Claimant '*to immediately withdraw [their] SIEF survey otherwise [the Other Party] will contact the authorities for […] this second joint registration for the same substance*' and adds that '*[y]ou are […] free to contact us in case you want to register the substance.*'	
10.	14/10/2016	The Claimant states that '*REACH legal text define[s] substance an intermediate in different points […] while* [redacted] *and* [redacted] *are define[d] inside intermediate, that show that intermediate is not a kind of substance, can not be considered and defined as a substance and therefor OSOR principle is not harmed*'. The Claimant further writes that REACH legal text has different chapters for	Provided only by the Claimant

Ref. no.	Date	Content	Remark
		registrations of intermediates and full substances. The Claimant also states that '*[t]his fact has been confirmed in document: "Strengthening the OSOR principle – Information session on the updated registration process" published on ECHA website*'. The Claimant then informs that '*REACH IT allows you to create two JS, one for intermediate and one for full*'. In addition the Claimant writes that '*[f]ull registration cover both registrations […] but […] is up to the companies intended to register as intermediate use only under SCC to create an intermediate JS[…] together or joining available full registration*'. The Claimant again asks for '*intentions of the companies interested in registering as an intermediate*'. The Claimant expresses openness '*to discuss this fact and even about joining all "intermediate companies" to [the Other Party's] registration*'.	
11.	14/10/2016	The Claimant answers to the Other Party's message with the same content as document with Ref. no. 9 but about [redacted]. The Claimant states that they agree to join a full JSS that covers intermediate use '*always if a reasonable prize is set taking in consideration that [the Claimant's] requ[ire]ments are "available data"*'. The Claimant further writes that they have '*been asking for a detail cost list (as ECHA allows [them] to ask for) […] this an[d] another substances […] and [they have] never got[ten] an answer*'. The Claimant considers that the Other Party '*is not applying the fair and transparency requirements, being this enough to enable [the Claimant] to ini[t]iate a separated JSS*'.	Provided only by the Other Party
12.	25/10/2016	The Claimant repeats their query for '*individual cost to study [to the Other Party's] JS*' and informs that if the Claimant does not get '*this information before 27th [o]ctober [they] will proceed with the registration thro[ugh] an intermediate JS as [the Other Party is] not complying with the fair and transparency rules*'.	Email with same content bu [redacted] in the subject field and different sending time provided by the Other Party

[redacted]

Ref. no.	Date	Content	Remark
13.	25/10/2016	The Other Party encloses (not provided) '*cost sharing basis per registrant for intermediate use*' and states that they hope that '*this give[s] clarity on the data charged towards the intermediate registration*'. The Other Party also invites the Claimant to discuss with the Other Party in case of further queries.	Provided only by the Other Party
14.	25/10/2016	The Claimant states that '*[a]t first [they] could agree with the cost [the Other Party] indicate[d]*'. The Claimant further requests the Other Party to send '*the CLP classification and the reimbursement procedure*'. The Claimant also asks about administrative costs after 2018. The Claimant then writes that if they agree they '*would proceed to the payment*' and requests '*invo[ic]e and the bank data*'. The Claimant also asks for '(*cost, reimbursement and invo[ic]e*) *of the rest of substance [they have] required from [the Other Party]*'.	
15.	28/10/2016	The Other Party informs the Claimant of '*classification in [their] dossier*'. The Other Party also states that '*[t]he admin cost is one time cost and there will be no reimbursement for the same. [The Other Party has] not yet anticipated the admin cost after 2018*'.	Provided only by the Other Party
16.	31/10/2016	The Claimant requests again '*the same information*' for [redacted] and 3 other substances.	
17.	03/11/2016	The Claimant sends the Other Party a reminder for the document with Ref. no. 16.	
18.	04/11/2016	The Other Party informs that the intermediate Letter of Access costs is [redacted] '*with* [redacted]' and attaches cost calculation (not provided).	
19.	04/11/2016	The Claimant asks the Other Party for bank account ownership certificate so that the Claimant can '*start with the order*'.	

[redacted]

Ref. no.	Date	Content	Remark
20.	04/11/2016	The Other Party encloses the bank account ownership certificate (not provided). The Other Party also promises to send copy of SIEF agreement for the disputed substance on the same day '*to complete the formalities*'.	Provided only by the Other Party
21.	07/11/2016	The Claimant informs the Other Party that they have '*made the order*' and asks the Other Party to '*manage the token to proceed with [the Claimant's] registration*'.	
22.	15/11/2016	The Claimant informs the Other Party that the Claimant has realised that the Other Party has created '*intermediate JS […] without any kind of survey*' when the Claimant already had '*sent a survey […] to all […] SIEF members included [the Other Party] before [the Other Party's] JS creation and had not [gotten] answer from [the Other Party]*'. The Claimant further states that the Other Party's '*procedure is illegal as [the Other Party] do[es] not comply with REACH regulations in what refers to SIEF formation, LR nomination and data sharing*'. The Claimant requests the Other Party to '*regret in [their] procedure and solve this situation. Otherwise [the Claimant] would be force[d] to initiate an appellation against [the Other Party]*'.	
23.	16/11/2016	The Other Party apologises for delayed response and encloses SIEF agreement. The Other Party further promises to send '*invoice towards the LOA*' and '*JS details after receiving the copy of SIEF agreement along with the payment towards the LOA*'.	Provided only by the Other Party