[redacted]

Helsinki, 24 November 2016

The Claimant

[redacted]

Represented by

[redacted]

Copy to:
The Other Party

[redacted]

Represented by

[redacted]

Decision number: DSH-30-3-[redacted]-2016
Dispute reference number: DSH-30-3-[redacted]-2016
Name of the substance: [redacted]
EC number of the substance: [redacted]

DECISION ON A DATA SHARING DISPUTE

1. Decision

Based on Articles 11 of Regulation (EC) No 1907/2006 ('REACH Regulation')[1] and Article 3

[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]

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 does not grant you access to the joint submission requested from [redacted]

The reasons of this decision are set out in Annex I. Advice and further observations are provided in Annex II. The factual background of the dispute is described in Annex III.

2. Procedural history

On 6 September 2016, you submitted a claim concerning the failure to reach an agreement on data sharing with [redacted] 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 [redacted] to provide documentary evidence regarding the negotiations. They submitted the documentary evidence on 28 September 2019, as requested by ECHA.

3. 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

[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.

[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 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 started the negotiations on 17 November 2015 by requesting from the Other Party the cost for the letter of access (LoA) and the substance identification profile (SIP).[4] The Claimant also informed the Other Party that they had previously communicated to the potential registrants of the substance their intention to take over the lead registrant role and submit the joint registration. However, the Claimant was subsequently informed about the existing joint registration for the substance, which was submitted by the Other Party as lead registrant.

The Other Party provided to the Claimant the SIP, based on which the concentration range of the main constituent of the substance had been set to >=[redacted]%.[5] The Claimant requested the Other Party to lower the minimum concentration range for the main constituent of the substance to >=[redacted]%.[6] The Other Party however expressed its concerns for lowering the minimum concentration due to '*the similarity of the substance with other substances identified as potential* [redacted]'.[7] They nevertheless expressed the willingness to '*release a token and proceed with joint submission without sharing* [redacted] *data*'.

In response, the Claimant stated that '*by setting the purity level for the Substance Information Profile ("SIP") at* [redacted]*%, without objective justification,* [redacted] *has potentially acted in an anticompetitive way, because this level prevents other competitors, such as* [redacted]*, from joining* [redacted] *joint submission dossier*'.[8] They further stated that [redacted]

[4] See document with reference no. 2
[5] See document with reference no. 5
[6] See document with reference no. 10
[7] See document with reference no. 19
[8] See document with reference no. 22

[redacted]

is legitimate in its role as lead registrant under Article 11 of the REACH Regulation, since it notified and received the consent of several potential co-registrants of the Substance'. Accordingly, the Claimant requested the Other Party to agree on relinquishing the lead registrant's role to them within a certain deadline. They also declared that a failure of the Other Party to do so would force the Claimant *'to avail itself of the available legal and procedural means at its disposal'*.

In reply, the Other Party explained that its decision to opt for the higher purity level related to the *'manufacturing process* [of their substance]*, which is covered by confidentiality and intellectual property'.*[9] In relation to the submission of the joint registration, the Other Party stated that it *'received a new significant order for the Substance from a customer which required immediate action [..] In order to satisfy such request,* [redacted] *had to proceed without delay with the registration [..] that circumstance was not subject to disclosure to competitors within SIEF at the time'.* Nevertheless, the Other Party declared that they are '*prepared to cooperate with* [redacted] *and [..] open to discuss the issues at hand, including any data sharing as relevant. To this end [they] propose[d] to enter into a confidentiality agreement and arrange a meeting [..] to resolve amicably the issues at hand*'.

In response, the Claimant pointed out that *'the level of purity of substances registered under REACH should be set to* [redacted]*% [..] unless there is an objective reason to consider that there would be a difference in hazard or risk for purity levels higher than* [redacted]*%'.*[10] In addition, the Claimant stated that they did not '*see the usefulness of concluding a confidentiality agreement*' since they had already communicated a list of available tests for the substance to the Other Party.[11] Thus, they repeated their request that the Other Party relinquishes the lead registrant's role setting a new deadline.

In turn, the Other Party stated that they are '*the natural lead registrant in light of the higher tonnage and related earlier deadline for registration'.*[12] They also reiterated their '*request* [that the Claimant] *make*[s] *available* [their] *studies to* [redacted] *in order to assess the possible gaps and/or any difference of properties*'. The Other Party also declared that they are '*fully prepared to cooperate with* [redacted] *for the joint registration dossier and that it is open to discuss the issues at hand, including any data sharing as relevant, in order to resolve amicably the issues at hand [and] assess the extent to which* [redacted] *studies on the* [redacted]*% purity level could be relevant for the* [redacted] *purity level or on the contrary would require an opt-out from* [redacted] *to cover its own purity profile of* [redacted]

The Claimant replied that '*the immediate need to meet an order is no valid reason for acting unilaterally without informing the other SIEF members.* [redacted] *was under a duty under REACH to secure consent from the SIEF members prior to proceeding with registration*'.[13] They repeated that the Other Party had not offered any objective justification for setting a higher purity profile for the substance stating that [redacted] *unilateral and arbitrary conduct [..] amounts to anticompetitive foreclosure'.* They thus requested the Other Party to sign an agreement within a set deadline, allowing the Claimant to join the joint registration and becoming the lead registrant for the substance, failing which they declared their intention to seek available remedies before the relevant authorities.

The Other Party expressed its surprise for the receipt of that request and stated that this '*is unreasonable especially as you are asking our client to simply agree with the terms of your*

[9] See document with reference no. 26
[10] See document with reference no. 27
[11] See document with reference no. 10
[12] See document with reference no. 28
[13] See document with reference no. 29

[redacted]

client's earlier position by signing an agreement whereby [redacted] *would transfer the Lead Registrant status to* [redacted] *and allow* [redacted] *to opt out without any further discussion'*. [14] They stated that '[redacted] *is open to discuss with* [redacted] *the extent to which its studies on the* [redacted] *% purity level could be relevant for the* [redacted] *% purity level and vice-versa [and that]* [redacted] *has not addressed our client's request to make its studies available to* [redacted] *in order to assess possible gaps and/or any difference of properties between the two purity levels [..]'*. The Other Party also added that '*If needed our respective clients may appoint an independent third party expert to assist and find a technical compromise*'. They also made a suggestion for such a third party expressing the willingness to set up a meeting between the latter and the parties.

In its reply, the Claimant set a new deadline for the Other Party to provide the token to the joint registration and then allow them to become the lead registrant for the substance, failing which they declared their intention to submit a dispute to ECHA.[15] They expressed their urgency to register immediately and stated that [redacted] *is also open to discussing the relevance of the information to the joint submission [..] However, this is a totally separate matter and discussion, which cannot interfere with the ongoing negotiation or be made a precondition to providing the requested token*'.

In response, the Other Party stated that '*our client fails to understand the reason why your client is pushing so much for changing the Lead Registrant and why our client should simply accept it. There is in principle no obstacle for our clients to work in collaboration without changing the status of Lead Registrant*'.[16] The Other Party also informed the Claimant that they would send them shortly an agreement concerning the communication of the token to the joint submission. They also reiterated their openness to discuss with the Claimant the relevance of the parties' studies for their different purity profiles, also with the assistance of an independent third party expert, and '*agree on any sensible solution to combine dossiers and any relevant data compensation*'.

In turn, the Claimant repeated its request to the Other Party for the provision of the token to the joint submission based on their own contractual proposal setting a new deadline failing which they declared that they would file a dispute to ECHA.[17] They also pointed out that they are '*open to discuss the studies on which each company relies [..] but this discussion is separate from the urgent need [..] to register the Substance [..] since we've explained repeatedly that* [redacted] *does not request any data from* [redacted] *in order to register*'.

The Other Party replied that '*In the interest of time and as a matter of good will, our client is willing to use your contract template but would like to insert a few comments*'. [18] They also reiterated their proposal for the appointment of an independent third party that could review the list of studies and determine their relevance in relation to the different purity profiles.

In reply, the Claimant requested the Other Party to sign their proposed contract on joining the joint registration, and in which they had incorporated all requested changes setting a deadline of one day.[19] The Other Party indicated that it would not be able to revert to the Claimant within that timeline but only a few days later and reiterated its invitation to

[14] See document with reference no. 31
[15] See document with reference no. 32
[16] See document with reference no. 34
[17] See document with reference no. 35
[18] See document with reference no. 36
[19] See document with reference no. 37

[redacted]

discuss the difference in the purity profiles.[20]

The Claimant set a new deadline to the Other Party for signing the contract.[21] In the absence of a reply by the Other Party, on 6 September 2015 the Claimant communicated its intention to file a dispute to ECHA while declaring their openness '*to finding a rapid solution while the Agency will be examining the details of the dispute claim*'.[22]

Assessment

ECHA notes that the arguments of the Claimant during the negotiations were mainly concerning the joining of the joint registration and becoming the lead registrant for the substance. In contrast, ECHA notes that the arguments of the Other Party during the negotiations were mainly concerning agreeing on the data submitted jointly and the opting out possibility.

Concerning the carrying out the lead registrant's role, the refusal of the Other Party to relinquish that role to the Claimant was a point of controversy between the Parties that prevented them from finding an agreement on the conditions for access to the joint submission. Article 11 of the REACH Regulation requires that multiple registrants of the same substance agree on certain information submitted jointly. In case of disagreement on the representativeness of an information jointly submitted, Article 11(3)(c) or 19(2)(c) of the Regulation explicitly enables a registrant to submit that information separately (so-called opt out).

ECHA notes that, upon their own admittance, the Other Party had not sought the agreement of the other potential registrants for the substance before submitting the information on the substance. An agreement on the way to proceed with the joint submission and a prior discussion on the data submitted may prevent potential disagreements of subsequent registrants. Nevertheless, the absence of such discussion does not prevent subsequent registrants to agree later on the data submitted or to complete this data with further information. However, this necessarily requires a discussion between the existing registrants and the potential registrant on the representativeness of the information already submitted.

Accordingly, while ECHA recognises that the legitimacy of the lead registrant can be an important matter for the parties, this question did not prevent the Claimant from discussing the information already submitted and joining the joint submission. In that context, it is pointed out that, as a result of the Implementing Regulation on data sharing and joint submission, ECHA is setting 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. In Annex II to the present decision, ECHA explains the steps it would take to address the legitimacy of the lead registrant in the case at hand.

Concerning the agreement on the data submitted jointly, ECHA notes that all joint registrants must agree on the boundaries of the identity of the substance that is covered by the information jointly submitted. Accordingly, the scope of the compositional profile of the jointly registered substance may need to be refined following a request of a potential registrant.

[20] See document with reference no. 39
[21] See document with reference no. 40
[22] See document with reference no. 41

[redacted]

It is also pointed out that, even in case of disagreement on the information previously submitted by an existing registrant, the information to be submitted separately by a subsequent registrant, under Articles 11(3) or 19(2) of REACH, may be of relevance to all co-registrants. Thus, a potential registrant, who intends to invoke Articles 11(3) or 19(2) of REACH in order to opt-out, is expected to make this information available, upon request, to the existing registrants of the substance. When doing so however, the potential registrant may not disclose information that he considers to be commercially sensitive and is likely to cause him substantial commercial detriment.

In view of the higher purity profile of the substance in the existing joint registration, the Claimant was right to point out to the Other Party the specific compositional profile of the substance they intended to register, i.e. their lower purity profile. While the Claimant was correct in doing so, they nevertheless repeatedly turned down the Other Party's invitation to discuss the representativeness of the data already submitted for their specific compositional profile, and vice versa, possibly with the assistance of an independent third party too. Engaging in such discussion could have however helped the Parties to agree on the boundaries of the substance covered by the joint submission. In addition, it could have allowed them to identify whether the studies of the Claimant were of relevance for the registration of the substance with the higher purity profile, and vice versa. Thus, the refusal of the Claimant to discuss with the Other Party the data already submitted did not demonstrate that the Claimant made efforts in finding a sensible agreement on the conditions for access to the joint submission.

Further, towards the end of the negotiations, when the Claimant expressed their urgency to register the substance, the Other Party showed willingness to agree swiftly on the contractual arrangement proposed by the Claimant for the access to the joint submission. This demonstrates that, despite the Claimant's repeated refusal to engage in a meaningful discussion on the Parties' own available data for the substance, the Other Party made efforts to progress the negotiations and address the Claimant's urgent need to register.

Against this background, ECHA concludes that the Claimant did not exhaust every effort to reach an agreement with the Other Party on the conditions for access to the joint submission. Consequently, ECHA does not grant the Claimant the access to the joint submission. Both Parties are still obliged to comply with their obligation to make every effort to reach an agreement on the access to the joint submission after this decision and are thus strongly encouraged to continue their negotiations.

[redacted]

Annex II: ADVICE AND FURTHER OBSERVATIONS

Lead registrant role

ECHA notes the concerns raised by the Claimant in relation to the appointment of the Other Party in the lead registrant's role as well as the latter's own admittance of lack of prior communication with the other potential registrants for the substance. Thus, besides the present dispute, if the Claimant wishes to challenge the legitimacy of the lead registrant, they can request ECHA to take action. On this basis, ECHA can contact the other (potential) registrants for the substance to 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.

Joint submission obligation

ECHA stresses that all registrants of the same substance need to be part of the same joint registration. All information submitted for a given substance, whether jointly or separately (opt-out), forms a set of data describing the hazardous properties of and the risks associated with the substance, irrespective of the purity profile. Thus, to the extent that the information to be submitted separately (opt-out) defines the properties of the substance, it is of relevance to all registrants of that substance. Accordingly, a potential registrant is expected to share this information, upon request, with the other registrants of the substance. Nevertheless, when doing so, he may not disclose information that he considers to be commercially sensitive and is likely to cause him substantial commercial detriment.

[redacted]

Annex III: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

Ref. no.	Date	Content	Remark
1.	13/11/2014	The Claimant contacts pre-registrants '*as a SIEF Formation Facilitator*' for the substance with EC number [redacted] The Claimant communicates their intention to register the substance under [redacted] A questionnaire is attached with a deadline to respond by 5 December 2014. If the pre-registrants does not reply by the given deadline, they will be given dormant status and assumed to agree to the Claimant acting as Lead Registrant.	Only provided by the Claimant
2.	17/11/2015	The Claimant states that they are proceeding with their registration '*as Lead Registrant*' and that they have almost all data required for [redacted] The Claimant also informs that they have heard from a SIEF member that the Other Party has registered the substance '*as a Joint Submission*'. The Claimant further writes that they worry that they have '*missed some communication*' and wonder '*how it is best to proceed together*'. The Claimant also asks the Other Party for cost of Letter of Access and Substance Identification Profile in '*order to facilitate a decision for us and other SIEF members on next steps*'. The Claimant then invites the Other Party to express their '*thoughts on next steps*'.	
3.	09/12/2015	The Claimant asks if the Other Party has received their two messages and if the Other Party has any thoughts on how to proceed.	
4.	09/12/2015	The Other Party promises to respond the following day.	
5.	10/12/2015	The Other Party states that they never received the Claimant's communication in November 2014. The Other Party informs that they have successfully completed [redacted]	

Ref. no.	Date	Content	Remark
		tonnage band registration and asks for list of Claimant's tests. Substance Identification Profile (SIP) is attached. SIP defines the concentration range of the main constituent as [redacted] %. The Other Party promises to provide data sharing agreement *'within Christmas time'*.	Only provided by the Claimant
6.	10/12/2015	The Claimant states that they will study SIP and get back to the Other Party.	
7.	17/12/2015	The Other Party repeats their request for list of the tests the Claimant has performed on the substance.	
8.	18/12/2015	The Claimant promises to get back to the Other Party soon concerning the data list and asks why the registration of the substance is listed as [redacted] in the REACH database while in their email the Other Party refers to tonnage band [redacted]	
9.	18/12/2015	The Other Party states that they have requested ECHA to correct tonnage band.	
10.	14/01/2016	The Claimant attaches a *'list of available tests for the subject compound*. The Claimant writes that they have studied the SIP and requests lowering minimum concentration to [redacted] %. The Claimant further asks for approximate Letter of Access cost for tonnage band [redacted]	
11.	20/01/2016	The Claimant asks if the Other Party received email of 14 January 2016.	
12.	20/01/2016	The Other Party confirms receipt of email *'with the list of performed test'*.	
13.	28/01/2016	The Claimant requests for an update because they are *'concerned about timing and also about the SIP'*	

14.	28/01/2016	The Other Party asks for more information on the Claimant's concerns on the SIP and for confirmation that tests have been performed on the same substance.	Only provided by the Claimant
15.	28/01/2016	The Claimant informs that testing was performed on the same substance. The Claimant also wonders if Joint Submission is possible if the specification cannot be changed. The Claimant expects that the specification is adjustable '*as usual in a SIEF*'.	
16.	29/01/2016	The Other Party asks for the Claimant's proposal regarding the SIP specification.	
17.	29/01/2016	The Claimant stresses that they do not propose any other changes to the SIP than lowering the minimum concentration and asks to know in case there is any reason for not lowering it.	
18.	08/02/2016	The Claimant requests for an update on next steps and on the schedule.	
19.	09/02/2016	The Other Party expresses their concern of the substance's similarity with other substances identified as potential [redacted]. The Other Party further states that without knowing '*nature of impurities in other products it is dangerous to define* [redacted] *purity as requirement*'. They write that they lower purity to [redacted]. The Other Party also communicates willingness to release a token and proceed 'without sharing [redacted] data'.	
20.	09/02/2016	The Claimant asks if the Other Party meant to lower minimum concentration to [redacted] instead of [redacted]	
21.	10/02/2016	The Other Party writes that they misread the minimum purity indicated in the SIP. The Other Party refuses to lower purity from [redacted].	
22.	15/03/2016	The Claimant requests the Other Party to agree on transferring Lead Registrant role to the Claimant within two weeks. The Claimant states that failure to agree could be considered as the Other Party infringing REACH and would be potential anticompetitive behaviour.	

		The Claimant points out that the Other Party has violated REACH Article 11 by not requesting consent of other potential registrants before acting as Lead Registrant. The Claimant also remarks that the Other Party has breached REACH Article 30 by not asking if SIEF members have vertebrate animal studies. The Claimant writes that based on the information on ECHA's dissemination website at least [redacted] vertebrate studies were performed in [redacted] even though the Claimant already had relevant information. The Claimant further writes that 'by setting *the purity level for the Substance Information Profile ("SIP") at* [redacted]*, without objective justification,* [redacted] *has potentially acted in an anticompetitive way, because this level prevents other competitors, such as* [redacted] *from joining* [redacted] *joint submission dossier*'. The Claimant then states that '[redacted] *is legitimate in its role as lead registrant under Article 11 of the REACH Regulation, since it notified and received the consent of several potential co-registrants of the Substance*'. In addition the Claimant '*has rights to substantial data generated on the Substance itself*' whereas, according to '*information publicly available on the ECHA dissemination website*', the Other Party seems to rely on '*arguments supporting read-across*'. The Claimant informs the Other Party that they '*will have no other opportunity but to avail itself of the available legal and procedural means at its disposal*'.	Only provided by the Claimant
23.	01/04/2016	The Other Party acknowledges receipt of the Claimant's communication of 15 March 2016 and promises to answer '*early next week*'.	
24.	08/04/2016	The Claimant asks if the Other Party will reply on the same week.	
25.	13/04/2016	The Other Party promises to send reply letter on the following day.	
26.	14/04/2016	The Other Party explains to the Claimant that they had '*received a new significant order for the Substance from a customer which required immediate action [..] In order to satisfy such request,* [redacted] *had to proceed without delay with the registration'* in the tonnage band [redacted] and that this '*circumstance was not subject to disclosure to competitors within SIEF at the time'.* The Other Party considers it logical for themselves to be Lead Registrant '*for the more immediate*	Attached letter dated 13/04 /2016

		registration deadline' due to higher tonnage band and because Other Party is a '*leading economic operator of the Substance*'. The Other Party had not received the Claimant's '*initial email in good order*'. The Other Party had to react promptly to '*meet its customer's order*' and registration duties. The Other Party states that they are interested in registration for substance production up to [redacted] and that the [redacted] '*purity level relates to the manufacturing process, which is covered by confidentiality and intellectual property*'. The Other Party rejects the allegations on possible violations of REACH and/or competitions laws and finds some allegations even '*slightly contradictory*'. The Other Party states that the Claimant '*does not specify whether its access rights relate to the same Substance and are transferrable to third parties such as [the Other Party]*'. Nevertheless, the Other Party declared that '*is prepared to cooperate with [redacted] and [..] that it is open to discuss the issues at hand, including any data sharing as relevant. To this end [they] propose[d] to enter into a confidentiality agreement and arrange a meeting [..] to resolve amicably the issues at hand*'.	
27.	10/05/2016	The Claimant states that issue of the dispute is lack of '*objective reason to arbitrarily limit*' the SIP of the Joint Submission dossier above [redacted]%. The Other Party could specify higher purity level '*in its individual part*' of the Joint Submission dossier. The Claimant continues that '*the level of purity of substances registered under REACH should be set to [redacted]% […] unless there is an objective reason to consider that there would be a difference in hazard or risk for purity levels higher than [redacted]%*'. The Claimant further states that the Other Party prevents the access to the Joint Submission from the registrants with [redacted]% purity of the substance and is hence potentially restricting competition. The Claimant states that the Other Party violated Article 11 of REACH when it adopted the lead registrant role without consulting other potential registrants, pre-registrants and SIEF members. Concerning the studies available for the Claimant, they state that they have already given the Other Party a list of their studies and indicated that the actual substance was tested. Therefore the Claimant indicated that they did not '*see the usefulness*	

		of concluding a confidentiality agreement' since no confidential information needs to be exchanged. The Claimant further requests the Other Party to take steps in REACH-IT for Lead Registrant role transfer to the Claimant by 25 May 2016 or else the Claimant '*will avail itself of the available legal and procedural means at its disposal*'.	

28.	26/05/2016	The Other Party states that their whole substance assessment is based on [redacted]% purity. Their '*dossier shows a safety*' at this purity level. They cannot take responsibility for a lower purity. The Claimant can seek '*separate risk assessment*' with lower purity and present it in the context of the same dossier as the Claimant acknowledges in their letter of 10 May 2016 albeit by reference to higher purity. The Other Party further writes that they do not see justification for the Claimant to be Lead Registrant just because the Claimant proposes lower purity and had indicated intention earlier. They also state that they are '*the natural lead registrant in light of the higher tonnage and related earlier deadline for registration*'. The Other Party stresses that the Claimant may have [redacted]' that are immaterial for the Other Party. The Other Party also reiterates their '*request* [that the Claimant] *make*[s] *available* [their] *studies to* [redacted] *in order to assess the possible gaps and/or any difference of properties*'. The Other Party also declares that they are '*fully prepared to cooperate with* [redacted] *for the joint registration dossier and that it is open to discuss the issues at hand, including any data sharing as relevant, in order to resolve amicably the issues at hand [and] assess the extent to which* [redacted] *studies on the* [redacted]*% purity level could be relevant for the* [redacted]*% purity level or on the contrary would require an opt-out from* [redacted] *to cover its own purity profile of* [redacted]*%*'.	
29.	28/07/2016	Claimant considers that the Other Party does not fulfil conditions to act as Lead Registrant because the Other Party does not have the assent of the other potential co-registrants. The Claimant states they will keep pursuing for Lead Registrant role. The Claimant continues that the Other Party did not at any time comment the purity profile or '*react when a consensus emerged to appoint [the Claimant] as lead*	

		registrant for the Substance in late 2014'. Furthermore, the Claimant considers that '*immediate need to meet an order is no valid reason for acting unilaterally without informing the other SIEF members*. The Claimant further writes that the Other Party offers no objective justification for refusing to lower purity level to [redacted]%. The Claimant states that the Other Party's '*unilateral and arbitrary conduct [..] amounts to anticompetitive foreclosure'*.' The Claimant also states that they are '*able to fulfil [their] registration requirements […] without need to refer to any of the studies, or information relied upon by [the Other Party]*'. The Claimant proposes that the Other Party delivers token after signature of attached SIEF agreement and issues invoice of [redacted] € by 5 August 2016. After the signature of the contract the Claimant expects that the Other Party allows the Claimant to become lead registrant. The Claimant threatens to '*seek appropriate remedies before the relevant authorities*' if the Other Party fails to send the signed agreement to the Claimant by the set deadline.	
30.	29/07/2016	The Claimant updates SIEF members on the status of the joint registration of the substance following the Claimant's appointment as Lead Registrant in November 2014 and the Other Party's unilateral registration. The Claimant describes steps they have taken so far. The Claimant also informs that ECHA confirms that lead '*cannot be self-appointed*'.	
31.	05/08/2016	The Other Party considers that the one week deadline '*is unreasonable especially as you are asking our client to simply agree with the terms of your client's earlier position by signing an agreement whereby* [redacted] *would transfer the Lead Registrant status to* [redacted] *and allow* [redacted] *to opt out without any further discussion'*. The Other Party argues that failure to react to Claimant's communication does not necessarily mean approval to appoint Claimant as Lead Registrant. The Other Party also states that participant with higher tonnage band is a more suitable Lead Registrant '*as confirmed by ECHA's guidance on this point*'. The Other Party rejects antitrust allegations, by reference to lowering purity level and the Claimant's registration deadline. The Other Party '*cannot be forced*' to	

		lower purity level and '*modify its whole dossier*', it is for the Claimant to prove safety at [redacted]%. The Other Party fails to understand the Claimant's justification for an opt-out and therefore they request more details. The Other Party states that '[redacted] *is open to discuss with* [redacted] *the extent to which its studies on the* [redacted]% *purity level could be relevant for the* [redacted]% *purity level and vice-versa* [and that] [redacted] *has not addressed our client's request to make its studies available to* [redacted] *in order to assess possible gaps and/or any difference of properties between the two purity levels [..]'*. The Other Party further adds that '*If needed our respective clients may appoint an independent third party expert to assist and find a technical compromise*'. They also make a suggestion for such a third party expressing the willingness to set up a meeting between the parties and that third party.	
32.	19/08/2016	The Claimant requests the Other Party for token and name of Joint Submission by 26 August 2016, failing which the Claimant will file a dispute to ECHA. The Claimant explains that they urgently need access to Joint Submission in [redacted] tonnage band. The Claimant repeats that they do not request access to Other Party's data, only to Joint Submission. The Claimant states that '[redacted] *is also open to discussing the relevance of the information to the joint submission* [..] *However, this is a totally separate matter and discussion, which cannot interfere with the ongoing negotiation or be made a precondition to providing the requested token*'. These issues can be discussed once the Claimant is part of the joint submission.	
33.	24/08/2016	The Other Party informs SIEF members that '*shortly all the necessary documents and information for members who want to register [the Substance] will be finalized*' and invites interested SIEF members to contact the Other Party.	Only provided by the Claimant
34.	26/08/2016	The Other Party states that the Claimant has never (i) inquired as to the cost of sharing the data submitted to ECHA; or (ii) '*attempted to initiate data sharing discussions*'. The Other Party considers Claimant's communication to all SIEF members except to the Other Party about intention to '*submit a separate dossier*' and take over Lead Registrant role '*rather aggressive*'. They state that '*our client fails to understand the reason why your client is pushing so much for changing the*	

		Lead Registrant and why our client should simply accept it. There is in principle no obstacle for our clients to work in collaboration without changing the status of Lead Registrant'. The Other Party fails to see why Lead Registrant role should be transferred since the Claimant has not registered the substance and thinks that it '*would entail confusion and risks*'. The Other Party informs that a SIEF member already has asked the Other Party about the Lead Registrant change. The Other Party finds this '*unhelpful*' for '*proper handling of the registration*'. The Other Party states that the token number and Joint Submission object '*cannot be communicated casually*', the Other Party needs assurance that the Claimant will not rely on or refer to the Other Party's data. The Other Party is preparing '*an agreement concerning the communication of the token number […] in the absence of data sharing / compensation agreement'* and it will be sent to the Claimant '*shortly for review and signature*'. The Other Party has circulated to all SIEF participants '*a draft agreement […] to bring clarity and formalise the current situation*'. Finally, the Other Party reiterates their willingness to provide an offer for a Letter of Access to the Claimant and their openness to discuss the relevance of the studies owned by each party, also with the assistance of an independent third party expert, and '*agree on any sensible solution to combine dossiers and any relevant data compensation*'.	
35.	26/08/2016	The Claimant states that '*assurances*' requested by the Other Party are already in agreement provided by the Claimant on 28 July 2016 and therefore new agreement is not needed. The Claimant attaches undertaking containing the '*assurances*'. The Claimant requests for token by 29 August 2016 or else they will file a dispute. The Claimant also writes that they sent communication of 29 July 2016, to which the Other Party seems to refer, to all SIEF members including the Other Party. The Claimant states that they are *'open to discuss the studies on which each company relies [..] but this discussion is separate from the urgent need [..] to register the Substance [..] since we've explained repeatedly that* [redacted] *does not request any data from* [redacted] *in order to register*'.	
36.	29/08/2016	The Other Party disagrees with the Claimant's deadline and considers the Claimant's threats '*unhelpful in context of good faith discussion [the parties] are supposed to be having*'.	

		The Other Party states that '*In the interest of time and as a matter of good will, our client is willing to use your contract template but would like to insert a few comments*'. Undertaking signed by the Claimant should be inserted or cross-referred in the contract as well as confirmation that the Claimant considers the substance to be the same and that the opt-out is under their own responsibility. The Other Party also requests confirmation that the data list sent by Claimant '*is still current*' and asks for price list and cost breakdown '*in accordance with Commission Implementing Regulation 2016/9*'. The Other Party then confirms that it has not received the Claimant's recent letter to SIEF members. Finally, the Other Party disagrees with the Claimant's statements that all the previous points raised by the Other Party have been addressed by the Claimant. The Other Party reiterates its invitation to the Claimant to indicate whether it agrees to appoint an independent third party to review the list of studies for their different purity profiles.	
37.	30/08/2016	The Claimant sends to the Other Party updated Agreement including changes concerning substance definition, the Claimant's undertaking and clauses on liability and time limit as proposed by the Other Party. The Claimant asks the Other Party to sign the Agreement or submit additionally proposed changes the following day. The other points raised in the Other Party's previous letter are not related to the issue at hand and will be addressed separately.	
38.	30/08/2016	The Claimant states that they have sent communication of 29 July 2016 to the address of the official contact point in latest SIEF contact list generated by REACH-IT. It is also the email account which the Other Party referred to it in its communication to SIEF participants 24 August 2016.	
39.	31/08/2019	The Other Party writes that they will not revert before '*mid-next week*'. Review of amendments to draft contract cannot be completed because key person is on holidays and '*will only be back next week*'. In the meantime, the Claimant could address the outstanding points. Problems with email addresses had occurred in the past but the Other Party is, '*in any event*' now aware of the letter	

[redacted]

40.	01/09/2016	The Claimant reiterates that getting token is urgent. Settlement by 31 August is now overdue and commercial damages to Claimant are being documented. The Other Party's key person's '*absence has not been raised so far*' whereas ECHA considered in the past that '*internal structure or working methods of data owner cannot be an excuse for not complying with its obligations under REACH*'. The Claimant agrees to wait for the validation and signature of the agreement until 5 September 2016.	Only provided by the Claimant
41.	06/09/2016	The Claimant informs the Other Party that they are filing a dispute claim with ECHA. The Claimant still prefers '*to reach an amicable settlement*' and declares their openness '*to finding a rapid solution while the Agency will be examining the details of the dispute claim*'.	