



The Claimant:

[Redacted]

Copy to the Other Party:

[Redacted]

represented by

[Redacted]

Sent via REACH-IT

Decision number: [Redacted]
Dispute reference number: [Redacted]
Name of the substance: [Redacted]
EC number of the substance: [Redacted]

DECISION ON A JOINT SUBMISSION DISPUTE

1. Decision

Based on Article 11 of Regulation (EC) No 1907/2006 ('REACH Regulation')¹, and Article 3 of Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH ('Commission Implementing Regulation')²,

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.


ECHA grants you access to the joint submission

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

2. Procedural history

On 25 July 2016, you (the 'Claimant') submitted a claim concerning the failure to reach an agreement on access to the joint submission with  represented by  (the 'Other Party') as well as the related documentary evidence to ECHA. To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA also requested the Other Party to provide documentary evidence regarding the negotiations. The Other Party submitted the documentary evidence on 17 August 2016.

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>.

4. Advice and further observations

ECHA reminds both parties that despite of the present decision they are still free to reach a voluntary agreement. Accordingly, ECHA strongly encourages the parties to negotiate further in order to reach an agreement that will be satisfactory for both parties.

Yours sincerely,

Christel Schilliger-Musset³

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.

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').

The Commission Implementing Regulation strengthened further the joint submission obligation. In particular, Article 3 confirms that, even in situation of opt-out within the meaning of Article 11(3) of the REACH Regulation, all registrants submitting data (endpoints) separately shall be part of one joint submission for the same substance. The objective is to encourage and foster discussions among the registrants of the same substance in view of ensuring the quality of the dossier. In practice, the existing registrants provide access to the joint submission to potential registrants of the same substance. The terms and conditions on this access are agreed freely among the concerned parties.

A failure to reach an agreement results in blocking the registration of the potential registrant since separate submission outside an existing joint submission for the same substance is not possible in accordance with the Commission Implementing Regulation. Therefore, a remedy is necessary to resolve the dispute.

In this regard, Article 3(1) of the Commission Implementing Regulation clarifies the duty of ECHA to ensure that all registrants of the same substance form part of the joint submission. Recitals 12 and 14 of the Commission Implementing Regulation reinforce this role of ECHA. This is underpinned in the operation of Titles II and III of the REACH Regulation, and in particular the mechanisms for data-sharing disputes.

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 the dispute to ECHA. Accordingly, a dispute brought to ECHA in that context implies that ECHA must 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 terms and conditions to access the joint submission.

After recalling the factual background of the present dispute, ECHA provides the detailed outcome of the informed and balanced assessment of the efforts made by [REDACTED] (the 'Claimant') and [REDACTED] represented by [REDACTED] (the 'Other Party').

Factual background

The Claimant initiated the negotiations with their email of 10 January 2015⁴, requesting a Letter of Access (LoA) cost-breakdown in the [REDACTED] tpa band. With their next email⁵, they asked for a full explanation of the costs and cost-sharing mechanism. They announced the possibility of opting-out if they did not receive a reply.

In the following⁶, the Other Party informed that the total dossier cost amounted to [REDACTED] Euro for a dossier in the tonnage band above [REDACTED] tpa. They further indicated that the price included the costs from their technical consultants (IUCLID & CSR) and that the costs for

⁴ See document reference no. 1

⁵ See document reference no. 2

⁶ See document references no. 3 and 5

data was only [REDACTED] Euro out of [REDACTED] Euro total costs.

The Claimant rejected⁷ the price of the LoA and made a counter-offer of [REDACTED] Euro for a volume band of [REDACTED] tpa.

The Other Party reiterated their initial offer and provided additional information regarding the cost calculation⁸.

On the following day, the Claimant confirmed their disagreement and requested⁹ further information on the underlying cost items of the LoA.

In the absence of reply from the Other Party to this request, the Claimant communicated their decision¹⁰ to opt-out from the jointly submitted data and requested a token to access the joint submission while relying fully on their own data.

The Other Party provided additional information on the LoA costs and expressed their readiness to explain in further detail and to share the minutes of meetings justifying the non-study costs¹¹. They informed¹² that access to the joint submission was only possible via a LoA compensating the jointly submitted data or, in case of opt-out, would require a decision of the Consortium Steering Committee. After the Claimant provided two letters of ECHA which confirmed that opting-out from (parts of) the jointly submitted does not release the registrants from the obligation to form a joint submission¹³, the Other Party later agreed¹⁴ to issue a token for a fee of [REDACTED] Euro and provided a draft token agreement as contractual basis.

While the Claimant disagreed with the proposed amount, they decided to accept¹⁵ the requested token charge in order to receive the token without delay. However, in the following¹⁶ the parties disagreed on the content of the token agreement, mainly on two clauses (f and g) seeking to protect intellectual property rights ('IPR') contained in the joint submission. According to this, the Claimant would be requested to *'pay [the Other Party] [REDACTED] Euro [...] as liquidated damages'* should the Claimant misuse the token.

The Claimant sent their dataset¹⁷ to the Other Party to allow them to identify potential IPR issues in their opt-out dossier. The Other Party provided justifications for the two contested clauses and informed the Claimant that they will have a look at the documents provided¹⁸.

The Claimant further explained their disagreement and proposed an alternative wording of the contested clauses¹⁹. It was rejected by the Other Party²⁰ who further insisted on the

⁷ See document reference no. 6

⁸ See document reference no. 11

⁹ See document reference no. 12

¹⁰ See document reference no. 13

¹¹ See document references no. 18 and 20

¹² See document references no. 18 and 20

¹³ See document references no. 14, 18 and 20

¹⁴ See document references no. 23 and 27

¹⁵ See document reference no. 28

¹⁶ See document references no. 28, 30, 31, 32 and 33

¹⁷ See document reference no. 28

¹⁸ See document reference no. 30

¹⁹ See document reference no. 31

initially proposed wording and informed that they will not take a position on the Claimant's dataset.

On 25 July 2016 based on the failure to find an agreement on the contested clauses, the Claimant informed the Other Party of their intention to file a dispute to ECHA.²¹ The present dispute was submitted by the Claimant on the same day.

For its assessment, ECHA only considers the negotiations up to the moment the dispute was filed, i.e. up to 25 July 2016, and cannot take into consideration arguments or justifications that were not made during those negotiations.

Assessment

At the outset, ECHA observes that the subject of the negotiations changed over the time, from a request to share data to a request for access to the joint submission.

In the first phase of the negotiations, ECHA notes that the parties discussed sharing of costs in relation to the studies submitted in the joint dossier. The Claimant disagreed with the price quotation provided by the Other Party, namely with regard to the non-study costs, justified their disagreement, and made a counter-offer for which they provided the calculation and explanations²². In reply, the Other Party provided further information on the LoA price, especially concerning non-study costs²³.

ECHA highlights that the Claimant has the right to receive sufficient information to enable them to assess whether the requested price is fair, transparent and non-discriminatory. This is underlined by the Commission Implementing Regulation 2016/9, which requires the existing registrants to provide an itemisation of all costs, to enable the parties to base their negotiations on objective criteria. Therefore, upon request, registrants need to provide justifications and address the concerns raised by the potential registrants. ECHA further points out that the requirement to provide justifications for all cost items also covers non-study costs.

However, since no agreement could be found on the LoA, and pending a response of the Other Party, the Claimant changed their strategy and decided to make use of the rights granted under Article 11(3) of the REACH Regulation. ECHA notes that this is in line with the above-mentioned Commission Implementing Regulation 2016/9, which clarifies a registrant's right to submit some or all data separately while being part of the joint submission.

The negotiations consequently shifted on the sole access to the joint submission.

At the outset, it is worth underlining that each registrant is individually responsible for their registration and the information they chose to rely on, including opting out. Existing registrants cannot prevent a potential registrant from submitting some or all information separately by refusing them access to the joint submission.

²⁰ See document reference no. 32

²¹ See document reference no. 33

²² See document references no. 4, 6 and 12

²³ See document references no. 3, 5, 11 and 14

In the present case, ECHA notes that the Other Party initially refused to issue a token for an opt-out registration²⁴.

The Claimant sought ECHA's clarification regarding the possibility to opt-out and shared ECHA's communications with the Other Party. The latter subsequently agreed that the Claimant should receive a token to submit their opt-out information²⁵. They proposed a price for a token without a right to rely on any of the jointly submitted data. The Claimant accepted this price although they found it high.

ECHA is of the opinion that the Claimant demonstrated a sign of compromise and effort by accepting to pay the price as proposed²⁶. Making a concession to enable negotiations to proceed is part of making every effort to reach an agreement.

ECHA therefore considers that both parties made efforts to reach an agreement on the price of the token.

However, ECHA observes that the contested clauses of the draft token agreement, which aimed at triggering financial penalties in case the Claimant breached intellectual property rights, became the unique source of disagreement preventing access to the joint submission.²⁷

ECHA acknowledges the Other Party's legitimate rights to protect the IPR related to the jointly submitted data.

In this regard, ECHA notes that the Claimant drafted an alternative wording of the contested clauses and intended to address the concerns of the Other Party by disclosing their opt-out dataset to allow the Other Party to assess upfront whether there were any IPR issues with their dossier²⁸. In ECHA's view, this demonstrates the Claimant's efforts to find a compromise to satisfy the Other Party's concerns.

While the Other Party had initially agreed to review the Claimant's dataset, they later refused²⁹ to examine the dossier or take any position on possible IPR issues without explaining the reasons for which they withdrew from their initial intention to assess the Claimant's dossier.

ECHA notes further that the Other Party did not engage into discussing the alternative wording proposed by the Claimant but merely insisted on the originally proposed clauses³⁰. It follows that, on the IPR issue, ECHA considers that the Other Party did not make every effort to find a solution.

Overall, in the assessment of efforts during the second phase of the negotiations, ECHA

²⁴ See document references no. 14, 18 and 20

²⁵ See document references no. 23 and 27

²⁶ See document reference no. 28

²⁷ See document references no. 28, 30, 31, 32 and 33

²⁸ See document reference no. 28

²⁹ See document reference no. 32

³⁰ See document references no. 30 and 32

finds that both parties made efforts to agree on the token price³¹. However, the refusal of the Other Party to discuss the wording of the contested clauses and the refusal to examine the Claimant's dataset resulted in blocking the negotiations.³² This prevented the Claimant from registering, and, consequently, entering the market. The Claimant made use of the dispute mechanism at ECHA as a measure of a last resort in order to be able to comply with the joint submission obligation.

Conclusion

Based on the above, ECHA concludes that the Other Party did not make every effort; while the Claimant made every effort to reach an agreement on access to the joint submission.

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

Lastly, the present decision is without prejudice to the completeness and compliance of the data submitted separately by the Claimant to fulfil their registration obligations under REACH Regulation.

³¹ See document reference no. 28

³² See document reference no. 30

Annex II: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

| Ref. no. | Date | Content | Remark |
|----------|------------|---|---------------------------------|
| 1. | 10/01/2015 | First contact by the Claimant asking for the 'LOA cost-breakdown [...] in the [REDACTED] band'. | Attachment not provided to ECHA |
| 2. | 28/01/2015 | The Claimant resends his request and reminds about their request regarding 'a full explanation of the costs, and cost-sharing mechanism, related to the Joint Submission' and expects a reply by 06/02/2016. They also write that if they were 'compelled to undertake an opt-out registration of [...] due to a failure on your part to respond to our requests, naturally this will be noted to our national Competent Authority, and potentially also to ECHA' | |
| 3. | 28/01/2015 | The Other Party informs that LoA prices have been updated 2013 and will again be updated 2018 <i>with possible reimbursements if applicable</i> . They quote 'total dossier cost' of [REDACTED] Euros for a dossier in the tonnage band above [REDACTED] tpa <i>with a high cost coming from our technical consultants (IUCLID & CSR)</i> . They further write that the LoAs for the lower tonnage bands are 'a percentage of the 2013 costs -70% for the volume band [REDACTED] -30% for the volume band [REDACTED] -Further 50% reduction for a TI and 2/3 reduction in case of on-site isolated'. | |
| 4. | 28/01/2015 | The Claimant states that they 'require much more detailed information on costs' and repeats the detailed request for 'existing, read-across and new study costs', 'technical consultant charges related to dossier and CSR creation' and 'all other admin and technical-related costs'. | |
| 5. | 28/01/2015 | The Other Party provides a table with 'anonymized' data, stating that 'data is a minor cost' and that 'non-data costs have been shared between [REDACTED] and [REDACTED] y. | |
| 6. | 11/09/2015 | The Claimant finds the LoA offer 'completely unacceptable' as the substance in question is 'a very | |



| Ref. no. | Date | Content | Remark |
|----------|------------|--|------------------------------|
| | | <i>common substance with a wealth of existing data', 'no new data was generated' and 'the administration-related costs are extraordinarily high'. According to their own calculations 'of a very "fair and reasonable" LOA charge' based on 'dossier generation', 'additional admin costs' and the 'number of existing registrants', the LoA should cost around €[REDACTED] for a [REDACTED] tpa to join the joint submission. That is their counter offer. They expect a reply within 7 working days.</i> | |
| 7. | 11/09/2015 | The Other Party acknowledges the response, agrees to check the information and promises to <i>'come back to [the Claimant] next week'</i> . | |
| 8. | 11/09/2015 | The Claimant agrees to receive the reply the following week. | Only provided by Other Party |
| 9. | 22/09/2015 | The Other Party asks for the extension of deadline for two days to be able to receive <i>'confirmation from our legal advisor'</i> . | |
| 10. | 22/09/2015 | The Claimant agrees to receive the reply in two days. | Only provided by Other Party |
| 11. | 24/09/2015 | The Other Party writes that they have adopted a <i>'cost-sharing mechanism that is fair, transparent and non-discriminatory'</i> . They also mention that the Claimant is questioning the <i>'costs of dossier preparation'</i> but not <i>'principles of the cost-sharing'</i> . They further explain that all related meetings are minuted and they are <i>'linked with concrete work on specific tasks connected with the dossier preparation'</i> . Finally, they ask about the basis of the Claimant's estimate for dossier preparation and what kind of detailed information should be further provided. | |
| 12. | 25/09/2015 | The Claimant writes they disagree with the quoted LoA price because of the <i>'extremely high administration-related charges, number of existing registrants, very low cost of existing data package, no new studies etc'</i> . They further state that their estimate for dossier preparation is based on their own experience as consortium managers that they can <i>'comfortably spend less than 50 hours in total managing more difficult substances'</i> . | |



| Ref. no. | Date | Content | Remark |
|----------|------------|--|--------|
| | | <p>In addition, they request a <i>'full breakdown of all major costs'</i> :</p> <ul style="list-style-type: none"> • <i>'Cost calculations for every existing study which was used in the lead dossier'</i> • <i>How do[es the Other Party] justify consortium meeting costs of [REDACTED]: ie how much was spent on hotels, travel (including flights), meetings, charges (and charging rate rate) for individual's time, how many individuals etc</i> • <i>What is meant by 'costs before starting consortium' + full breakdown of these costs</i> • <i>What did 'Experts 1&2 do to justify [REDACTED] of costs (full breakdown of costs required)</i> • <i>What did 'Internal Experts' do to justify [REDACTED] of costs (full breakdown of costs required)</i> • <i>What does 'Maintenance' at [REDACTED] involve'</i> | |
| 13. | 03/11/2015 | <p>The Claimant informs the Other Party that since no answer was received to the last request, they want to register <i>'with immediate effect'</i> as an opt-out, if the Other Party is not willing to accept the offered LoA price of [REDACTED]. They also request a token to the joint submission within 7 working days. Finally they inform that in case the Other Party does not supply the token, they will <i>'will refer this matter to ECHA, since a Lead Registrant has no right to exclude a SIEF member from a JS Submission; the LR must act in the best interests of all members, including those opting out'</i>.</p> | |
| 14. | 10/12/2015 | <p>The Other Party provides an overview of the LoA costs for all tonnage bands, cost-sharing between the different tonnage bands, and <i>'other costs related to the creation of the dossier'</i> (<i>'Consultancy', 'Internal toxicology task force group', and 'Lead registration work on the dossier preparation'</i>). Further, they list the costs assigned to the <i>'value of the work of Consortium Members'</i> including a list of meetings.</p> <p>They ask whether the Claimant <i>'agree[s] to pay the price demanded by the consortium for the LoA, or [...] want[s] to maintain [their] position'</i>, and state that in case the Claimant wants to carry on with their intention to register as an opt-out the official answer will have to be provided after the <i>'Consortium Steering Committee meeting'</i> is convoked.</p> | |
| 15. | 12/01/2016 | <p>The Claimant regrets that the Other Party is not <i>'willing to negotiate on fair LOA costs'</i> and doesn't seem to <i>'have any intention of negotiating in future'</i>. They inform the OP that they are ready to submit their opt-out dossier and that they have raised this issue with ECHA and received a reply confirming their right to submit an opt-out dossier while remaining member of the joint submission. Also the Other</p> | |



| Ref. no. | Date | Content | Remark |
|----------|------------|---|--|
| | | Party has an opt-out intention and requests a token by 15 January 2016 to register as a part of the joint submission. | |
| 16. | 14/01/2016 | The Other Party requests the copy of communication from the Claimant with ECHA regarding the case. | |
| 17. | 14/01/2016 | The Claimant asks the Other Party to <i>'unconditionally guarantee'</i> that they will receive a token as they have to register <i>'now'</i> and then they can provide communication exchange with ECHA. | |
| 18. | 15/01/2016 | The Other Party considers they have <i>'extensively explained the cost breakdown'</i> and states that they are <i>'ready to address any further questions [the Claimant] may have on any aspect of the information [the Other Party] provided or indeed to send [the Claimant]any other relevant details [the Claimant]consider[s] necessary'</i> . They emphasise that the data sharing and provision of a token <i>'must be done on the basis of a duly executed SIEF Agreement and payment for the Letter of Access'</i> . They see it as a fair treatment of all SIEF members to not offer them <i>'a lower price for the Letter of Access'</i> , stating that the LoA price can be reduced only for the lower tonnage band. Finally, they ask again for the copy of communication with ECHA regarding the case. | |
| 19. | 19/01/2016 | <p>The Claimant writes that because of the <i>'grossly unfair LOA charges, we decided to opt out of all [...] lead dossier end-points and have now generated our own full opt-out [...] REACH dataset & dossier'</i> which is <i>'based on the wealth of data available in the public domain'</i>.</p> <p>The state that they <i>'are entitled to obtain the JS Token from [the Other Party] to enable us to submit our full opt out dataset / dossier, as a legitimate member of the [...] SIEF'</i>, highlighting that they <i>'do not have to pay for a Letter of Access for this to happen'</i>.</p> <p>They send the letter they have received from ECHA (reference ) and argue that they <i>'do not need a Letter of Access [..], [they] do not need any of the data [the Other Party] hold[s] and we do not need to pay [the Other Party] for it'</i>.</p> <p>They repeat the requests of a token and set a deadline of 22 January 2016 for the Other Party to provide it, and announce that they will provide their <i>'our opt-out dataset once the Token has been redeemed'</i> to the Other Party,.</p> | <p>Letter from ECHA ) provided by Other Party</p> |



| Ref. no. | Date | Content | Remark |
|----------|------------|--|--|
| 20. | 22/01/2016 | The Other Party repeats that Claimant did not question further the breakdown costs. They highlight that the Claimant can get access to the joint submission after LoA payment. Also they emphasise that they <i>'will not accept an individual submission of the same substance based on the OSOR principle'</i> . | |
| 21. | 20/04/2016 | The Claimant makes reference to communication with ECHA and provides summary of the situation: <i>'1. We are fully-opting out of all [...] lead-dossier endpoints for a [REDACTED] [...] REACH registration. 2. We do not need, and have no desire, to purchase a LOA or any data from you. 3. We have independently prepared our own [REDACTED] REACH dossier, without reference to privately-held data. 4. We now wish to submit this dossier via REACH-IT. 5. We are requesting the JS Token from you in order that we may submit our dossier and obtain our [...] REACH registration.'</i> Additionally they <i>'accept ECHA's point where there may be a small charge with respect to issuing the Token, which [they] are prepared to pay provided it can be properly justified'.</i> Finally, they ask to receive the token <i>'in the near future'</i> . | Attachment (ECHA letter with reference [REDACTED] only provided by Other Party |
| 22. | 26/04/2016 | The Claimant requests a response <i>'within the next few days'</i> . | |
| 23. | 26/04/2016 | The Other Party explains that they work with a Lead Registrant on a contract and the fee to provide a token. | |
| 24. | 26/04/2016 | The Claimant confirms receipt. | |
| 25. | 04/05/2016 | The Claimant asks why the contract is not ready yet. | |
| 26. | 13/05/2016 | The Claimant informs that if <i>'the long-delayed issuing of this JS token is not progressed very soon'</i> they will submit a data sharing dispute within seven days they do not get the contract. | |
| 27. | 20/05/2016 | The Other Party comes back with the agreement for providing the token. They request [REDACTED] Euro for issuing the token, based on an estimate of the work required to <i>'create the SIEF, approve the LR [Lead Registrant] and create a Joint Submission in REACH-IT'</i> which is then | Token agreement not provided to ECHA |



| Ref. no. | Date | Content | Remark |
|----------|------------|--|------------------------------|
| | | divided by the number of 'LoA buyers' (and not by 'the total number of legal entities including affiliates')., | |
| 28. | 31/05/2016 | <p>The Claimant writes that the price for issuing the token is 'unnecessarily high, given that it's a simple 20 minute operation to provide a Token' but that they agree to pay the requested amount nevertheless 'to gain immediate access to the token'.</p> <p>They find however that two clauses (f and g) of the token agreement are 'completely unacceptable', as they 'in effect permit [the Other Party] to force an immediate and excessively large financial claim against us in the event that [the Other Party] believes – including wrongly – that we may have breached EU property or copyright rules'. Should the Other Party not agree to remove these 'offending clauses', the Claimant announces to bring a 'complaint to ECHA and the EU Commission competition authorities' and to inform 'Chemical Watch and others'.</p> <p>Further, they attach their opt-out dossier for the Other Party 'to review this dataset and highlight any truly legitimate examples of instances where it is thought we might have contravened EU property or copyright rules' and promise to 'make the necessary changes'.</p> | Dataset not provided to ECHA |
| 29. | 31/05/2016 | The Other Party acknowledges receipt of the comments from the Claimant and informs to come back 'shortly' after consulting with Lead Registrant. | |
| 30. | 22/06/2016 | <p>The OP writes that they are 'rather surprised by [the Claimant's] strong reaction and dare to believe that some misunderstanding might be at the basis thereof'. They state that the two clauses (f and g) the Claimant disagree about are in place to 'protect the studies, in particular the intellectual property rights' contained in the joint submission and in order 'to treat all registrants in a fair, transparent and non-discriminatory way'. According to the mentioned clauses, the Claimant would be requested to 'pay [the Other Party] [REDACTED] Euro [...] as liquidated damages' should the Claimant misuse the token.</p> <p>They write they 'will have a closer look' at the dataset provided by the Claimant and state that the disagreed clauses 'will not apply and should not be of any concern' if no intellectual property rights are breach.</p> <p>Finally, they underline that in addition to the disagreed clauses they 'retain the right to claim [...] further damages' and write that they 'will be compelled to take appropriate legal and other actions' should the Claimant inform the authorities or media as announced in their message of 31 May 2016.</p> | |



| Ref. no. | Date | Content | Remark |
|----------|------------|---|--------|
| 31. | 23/06/2016 | <p>The Claimant argues that the two disagreed clauses are <i>'unfair and punitive'</i> and would allow the Other Party to <i>'arbitrarily challenge any data [the Claimant] included in [their] opt-out dossier and demand an immediate payment'</i>. Additionally if <i>'inadvertently'</i> data owned by the Other Party are included, the full LoA price covering all end-points will have to be paid. They see this as <i>'grossly unfair'</i>.</p> <p>Regarding the IUCLID file with their opt-out dossier which they provided to the Other Party earlier, the Claimant request the Other Party to check the dossier now to avoid any copy right and intellectual rights breach consequences later.</p> <p>Therefore the Claimant proposes revised text for those two clauses, to <i>'protect the legitimate data-ownership rights'</i>, which <i>'take immediate steps to remove said data'</i> and <i>'legal or other appropriate actions'</i> as this would be <i>'much fairer, and more appropriate and proportionate'</i> and writes that their new proposal would be <i>'fairer, and more appropriate and proportionate compared to the financial-penalty clauses'</i> initially foreseen.</p> | |
| 32. | 06/07/2016 | <p>The Other Party acknowledges receipt of the IUCLID file which the Claimant intends to submit as part of the opt-out dossier. But with reference to the REACH provisions on legitimate possession of data, they write that they are not in a position <i>'to adopt any stance, of whatever nature, with respect to its content'</i>. They therefore reject the new wording of the disagreed clauses as proposed by the Claimant, and insist on signing the originally proposed token agreement.</p> | |
| 33. | 25/07/2016 | <p>The Claimant summarises the situation and informs about intention to involve ECHA, writing that agreement has been found to provide the token to the joint submission and on the respective fee, but that there is a disagreement on a clause allowing the Other Party <i>'to levy automatic and punitive financial penalties against [the Claimant] in the event that the [Other Party] dislikes anything in [the Claimant's] submitted opt-out dossier'</i>. They resend their alternative proposal for the disagreed clauses and highlight that they have provided the Other Party with their dataset to allow the Other Party to <i>'highlight any concerns [...] about possible intellectual property or copyright breaches'</i> before submission of the dossier. They further write that the Other Party refused to do so even though this <i>'simple step would have been very helpful to resolving our current impasse'</i>.</p> <p>Finally, they announce to get ECHA involved <i>'to resolve this matter'</i>.</p> | |



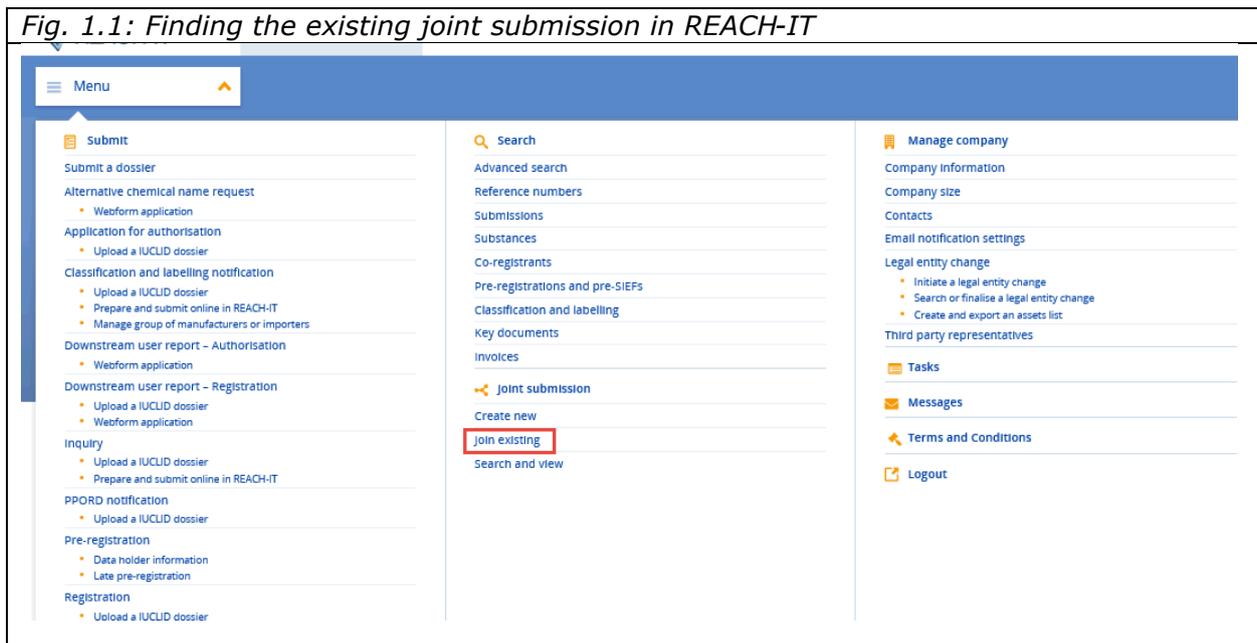
Annex III: INSTRUCTIONS ON HOW TO SUBMIT YOUR REGISTRATION DOSSIER AFTER THE RESOLUTION OF THE JOINT SUBMISSION DISPUTE PROCEDURE

Before submitting the IUCLID dossier to ECHA via REACH-IT, you need to sign up as a member of the joint submission in REACH-IT.

1. Find the existing joint submission

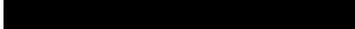
Log in to REACH-IT, and search for and join the existing joint submission via the search function.

Fig. 1.1: Finding the existing joint submission in REACH-IT



2. Provide joint submission name and security token

Complete the fields with the following information:

- Joint submission name: 
- Security token: 

3. Update your contact details, if needed

To ensure that your co-registrants are able to contact you, update your contact details and assign a responsible contact person within your company. This is crucial for the further communications with the other registrants of your substance. Remember to update the contact information in case the responsibilities in your company have changed.

4. Confirm membership of the joint submission

Review the information you have provided and confirm the joint submission membership.



Fig. 4.1: Review and confirm the your joint submission membership

Please review the joint submission membership confirmation:

Name and token:

Joint submission name: [redacted] [Edit](#)

Contact details

Contact person: [redacted] [Edit](#)

Are you ready to confirm your joint submission membership?

[If yes,click here to confirm your joint submission membership](#)

If not, you may edit the information of any step or **cancel** the joint submission membership.

 None of the information will be stored in REACH-IT if you choose to start over or cancel the joint submission membership.

[← Back to Contact details](#)

5. Submit your IUCLID dossier

After you have successfully joined the joint submission as a member, submit your opt-out IUCLID dossier to finalise the registration.

"ECHA reminds you that following Article 16 of Regulation (EC) No 1049/2001, the documents attached are subject to copyright protection."