ECHA
EUROPEAN CHEMICALS AGENCY

The Claimant
[redacted]

Copy to:
The Other Party
[redacted]

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

DECISION ON A DISPUTE

a) Decision

Based on Article 30(3) of Regulation (EC) No 1907/2006 ('REACH Regulation'),

ECHA grants you the permission to refer to the information you requested from the Existing Registrant, [redacted], of the above-mentioned substance.

According to Article 30(3) of REACH, the Existing Registrant shall have a claim on you for an equal share of the cost, which shall be enforceable in the national courts, provided that the full study report(s) is made available to you.

The reasons of this decision are set out in Annex I. An overview of the negotiations is provided in Annex II. The list of studies ECHA grants you permission to refer along with copies of (robust) study summaries can be found in Annex III and IV, respectively. Instructions on how to submit your registration dossier are provided in Annex V.

b) Procedural history

On 24 October 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 by 25 November 2016. The Other Party did not however submit any evidence to ECHA. Therefore, the assessment of this dispute is based only on the documentary evidence provided

by the Claimant. When requesting the Other Party to provide its evidence ECHA made the Other Party aware that if the Other Party would not make the requested information available to ECHA, the assessment would be conducted and the decision taken solely on the basis of the evidence provided by the Claimant.

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.

d) 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-Musset[1]

Director of Registration

[1] 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

Article 30(1) of the REACH Regulation sets out as a pre-requisite that SIEF '*participant(s) and the owner* [of the data] *shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way*'. In case of a dispute on the sharing of studies involving vertebrate animal testing which have already been submitted to ECHA by another registrant, Article 30(3) of the REACH Regulation requires ECHA to determine whether to grant the claimant a permission to refer to the information contained in the registration dossier, i.e. to the relevant studies. In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the documentary evidence on the negotiations as provided by the parties, to establish whether the parties have made every effort to reach an agreement on the sharing of studies and their costs in a fair, transparent and non-discriminatory way.

Factual background

On 3 July 2015, the Other Party contacted all the SIEF members, informing that it was the Lead Registrant and asking the companies to communicate their registration intentions[2]. On 7 July 2016, the Claimant informed the Other Party of their intention to register the substance in question for the tonnage band of [redacted] t/y[3].

On 30 October 2015 the Claimant asked for the cost of Letter of Access for the tonnage bands [redacted] t/y and 1[redacted] t/y[4]. The Other Party communicated to the Claimant on 2 November 2015 the costs for the tonnage bands [redacted] t/y, [redacted] t/y and [redacted] t/y[5].

In its email to the Other Party on 11 December 2015 the Claimant wrote that it '*would like to have the details of the LoA cost calculation. There is no detailed information [about it] in the SIEF agreement'*[6]. In the absence of any reply from the Other Party to this email, the Claimant asked again for the detailed costs on 9 February 2016[7]. Later on the same day, the Other Party promised to provide an answer by 15 February 2016[8].

The Other Party did not get back to the Claimant by the above-mentioned date. On 24 February 2016 the Claimant asked if the Other Party had '*any update to provide on the detailed LoA cost*'[9]. The Other Party replied on 26 February 2016 and informed that it as the Lead Registrant had received a final decision on a compliance check from ECHA and it needed to submit further information for [redacted] endpoints. In the same email of 26 February 2016, the Other Party updated the Letter of Access price for [redacted] t/y '*including the further cost by performing the mentioned test requested by ECHA*'. The Other Party then also provided the Claimant with a table where the costs were divided into three categories: '*Studies compensation'*, '*Dossier&CSR'* and '*Admin'*[10].

The Claimant replied, on the same day, that '*in fact*' it was requesting '*the detailed costs for studies compensation study by study*'[11]. The Claimant then sent reminders to the Other Party on 10 May 2016 and 26 May 2016 and asked again for '*the itemisation and justification of*

[3] See document Ref. no. 2
[3] See document Ref. no. 2
[4] See document Ref. no. 3
[5] See document Ref. no. 4
[6] See document Ref. no. 5. The negotiations provided to ECHA do not include any SIEF agreement.
[7] See document Ref. no. 6
[8] See document Ref. no. 7
[9] See document Ref. no. 8
[10] See document Ref. no. 9
[11] See document Ref. no. 10

data and any other costs' included in the Letter of Access and '*detailed informations concerning […] reimbursement mechanism*'. The Claimant announced on 10 May 2016 for the first time the possibility to use a data-sharing dispute if it did not receive an answer within one month[12].

The Other Party explained to the Claimant on 27 May 2016 that the Other Party was still awaiting the '*final quotation for the additional testing'* and that the '*LoA will be recalculated accordingly'*. The Other Party promised to give an answer soon[13].

The Claimant subsequently sent requests for itemisation of the costs on 8 June 2016, 21 June 2016 and 29 June 2016[14]. On 30 June 2016 the Other Party promised to send information '*later today*'[15].

The Claimant sent further reminders to the Other Party on 6 July 2016, 28 July 2016, 9 August 2016, 15 September 2016, 5 October 2016 and 12 October 2016 asking for the '*costs, study by study*' and emphasizing the urgency of the request[16]. In the emails of 5 and 12 October 2016, the Claimant wrote that they tried to contact the Other Party by phone but did not manage to reach the appropriate person and were not contacted back[17]. On 14 October 2016 the Claimant informed the Other Party that it would '*initiate a dispute claim to ECHA' 'if [it] did not get and answer by October 19*'[18]. The Claimant submitted the related dispute claim on 24 October 2016.

Assessment

In order to agree on fair, transparent and non-discriminatory sharing of data and costs, the parties need to find a common understanding of the costs of the data. Communicating on the cost calculation is therefore a pre-requirement for successful data-sharing negotiations. Following the Commission Implementing Regulation (EC) 2016/9, a potential registrant has the right to receive a meaningful cost break down (itemisation) which links cost items with data requirements and provides a justification for each cost item. The aim of the Implementing Regulation is to facilitate fair, transparent and non-discriminatory data-sharing process by creating clearness regarding all the data to be shared. Article 2 of the Implementing Regulation therefore foresees an itemisation of all costs, past, present and future. The information provided must be detailed enough to allow the potential registrant to assess the specific need of the studies, their individual costs and the relevance of administrative costs. The Implementing Regulation specifies that this cost itemisation must be provided to the potential registrant without undue delay.

During the negotiations, the Claimant requested numerously (by email reminders and phone calls) for details of the Letter of Access cost calculation as this information was not available in the SIEF agreement[19]. The Claimant emphasised the necessity of having the information about the detailed costs for the studies compensation, study by study, during the entire negotiation process of almost a year.

The Other Party provided in the beginning of the negotiations the Letter of Access prices for

[12] See document Ref. no. 11, 12
[13] See document Ref. no. 13
[14] See documents Ref. no. 14, 16, 17, 18
[15] See document Ref. no. 19
[16] See documents Ref. no. 20, 21, 22, 23, 24, 25
[17] See document Ref. no. 24, 25
[18] See document Ref. no. 26
[19] See documents Ref. no. 5, 6, 8, 10, 11, 12, 14, 16, 17, 18, 20, 21, 22, 23, 25, 26

the substance in question for [redacted] different tonnage bands[20]. These prices did not however include any detailed cost itemisation. The only table of costs, which was received from the Other Party during the negotiations, is mentioned in an email dated 26 February 2016[21]. However, the division of the costs it shows, in three general and undefined categories without a study by study break down, could not enable the Claimant to get a clear understanding of the data to be shared, their need and their corresponding costs. The Claimant replied on 26 February 2016 that its request was for '*the detailed costs for the studies compensation, study by study*'[22]. The Other Party never provided detailed cost break down, despite having promised to do so several times[23].

The only explanation that the Other Party communicated for the delay to provide the cost break down was that they had received a final decision on compliance check from ECHA. The Other Party indeed indicated in an email of 27 May 2016 that they were '*waiting for the final quotation for the additional testing*'[24]. However, this justification was not explained further and seems contradictory with the Other Party's previous email of 26 February 2016, in which it indicated that the given prices '*includ[ed] the further costs by performing the mentioned test requested by ECHA*'[25]. Moreover, the Other Party could have provided itemisation for the data that was not affected by the compliance check decision. Furthermore, the additionally performed studies were only relevant for the [redacted] tonnage bands and the change of the price of the Letter of Access only affected the tonnage band [redacted] t/y (while the Claimant asked for cost break down for [redacted] t/y and [redacted] t/y). The compliance check decision does not justify not providing a cost break down for almost one year.

Furthermore, ECHA notes that the Other Party remained silent for almost 4 months before the launching of the dispute. The Other Party's last email of 30 June 2016 indicated that '*all information*' would be sent later on the same day[26]. Following this email, the Other Party ignored however all the Claimant's attempts to progress with the negotiations, as well as the Claimant's mention of the urgency of registering the substance[27], until the Claimant launched the dispute on 24 October 2016 (after informing the Other Party of its intention[28]).

ECHA considers that the Claimant made every effort to reach an agreement with the Other Party and to understand the Letter of Access cost. Due to the lack of reply from the Other Party on the cost itemisation for almost a year, the Claimant did not even have the ground to start the negotiations. By failing to provide a cost itemisation without undue delay, the Other Party did not fulfil an explicit obligation from the Commission Implementing Regulation (EC) 2016/9 to provide a cost break down. Therefore, the Other Party did not make every effort to reach an agreement on data sharing with the Claimant.

Conclusion

Based on the above, ECHA concludes that the Other Party did not make every effort to reach an agreement to share data. The Other Party did not provide the Claimant with a cost itemisation to enable them to assess whether the Letter of Access price is fair, transparent and non-discriminatory.

[20] See document Ref. no. 4
[21] See document Ref. no. 9
[22] See document Ref. no. 10
[23] See documents Ref. no. 7, 13, 19
[24] See document Ref. no. 13
[25] See document Ref. no. 9
[26] See document Ref. no. 19
[27] See documents Ref. no. 22, 23, 25, 26
[28] See documents Ref. no. 11, 26

Against this background, the Claimant made every effort to find an agreement and filed the data sharing dispute as a measure of last resort. Therefore, ECHA grants the Claimant a permission to refer to the [redacted] studies submitted by the Other Party for the [redacted] t/y band, which is the tonnage band indicated in the Claimant's dispute claim and which was covered by the negotiations with the Other Party[29]. These studies are listed in Annex III to the present decision.

[29] See documents Ref. no. 2, 3

Annex II: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

CHRONOLOGY TABLE		
Reference number	**Submission date**	**Article**
[redacted]	24/10/2016	30(3)

Ref. no.	Date	Content
1.	03/07/2015	The other party contacts all the SIEF members and informs them that they are the lead registrant and ask the companies about their registration intention with deadline 20/07/2015.
2.	07/07/2016	[redacted] (the Claimant) informs the Other Party of their intention to register the substance 1[redacted] for the [redacted] t/a.
3.	30/10/2015	The Claimant asks for the Letter of Access costs for tonnage bands [redacted] t/a and [redacted] t/a.
4.	02/11/2015	The other party provides the prices for the Letter of Access for the [redacted] different tonnage bands: [redacted] euros [redacted] euros [redacted] euros

Ref. no.	Date	Content
5.	11/12/2015	The Claimant requests the details for the Letter of Access cost calculation. In particular the Claimant asks if the Other Party applies risk premium and a rebate for REACH only use.
6.	09/02/2016	The Claimant resends its request of 11/12/2015 and requests again the details of the Letter of Access costs.
7.	09/02/2016	The Other Party promises to provide the detailed Letter of Access cost and the data sharing agreement by 15/02/2016
8.	24/02/2016	The Claimant sends second reminder to the other party and asks again for the detailed Letter of Access costs.
9.	26/02/2016	The Other Party replies that they as the lead registrant for the substance in question have received a final decision on compliance check from ECHA and they were requested to submit further information on [redacted] endpoints. For this reason the Other Party has recalculated the Letter of Access price and communicates the new price for each tonnage band: [redacted]euros [redacted] euros [redacted]. The Other Party attaches a table with the costs divided in three categories: “Studies compensation”, “Dossier&CSR”, “Admin”
10.	26/02/2016	The Claimant requests the details of the compensation for the studies study by study.
11.	10/05/2016	The Claimant requests again the itemisation and justification of data and any other costs included in the Letter of Access prices. The Claimant announces for the first time that they intent to use a data-sharing dispute if they do not receive an answer

Ref. no.	Date	Content
		within one month.
12.	26/05/2016	The Claimant sends another reminder and asks again for the detailed information concerning the costs of the studies.
13.	27/05/2016	The Other Party informs that they are waiting for final quotation for additional tests and will then re-evaluate the price of the Letter of Access. The Other Party states that they think “the final price will be lower” than the price communicated on 26/02/2016. The other party asks the claimant for patience and promises to give an answer soon.
14.	08/06/2016	The Claimant requests again an answer from the Other Party.
15.	08/06/2016	The Other Party promises to reply to the Claimant on 12/06/2016.
16.	08/06/2016	The Claimant asks for the information as soon as possible since they are expecting the reply since December 2015.
17.	21/06/2016	The Claimant repeats their request for information about the detailed costs study by study.
18.	29/06/2016	The Claimant reminds the other party that they are awaiting an answer since 27/05/2016 and asks again about the costs of the Letter of Access study by study
19.	30/06/2016	The Other Party apologises for the delay and promises to send information later on during the day.
20.	06/07/2016	The Claimant asks again about the costs of the Letter of Access study by study
21.	28/07/2016	The Claimant sends another reminder and asks again about the itemisation of the studies.
22.	09/08/2016	The Claimant sends another reminder and emphasizes the fact that they have tried to get information about the price of the Letter of Access since February 2016. The Claimant also states that now the registration of the substance becomes urgent.

Ref. no.	Date	Content
23.	15/09/2016	The Claimant informs the Other Party that they have tried to reach them over the phone without success. The Claimant asks for urgent feedback and emphasizes the long period they have been awaiting an answer and as well the fact that the Other Party constantly promises a reply and never sends one.
24.	05/10/2016	The Claimant informs the other party that they have spoken on the phone with two colleagues of the Other Party's contact person and they have been promised to receive a call back from the Other Party. The Claimant asks for an answer.
25.	12/10/2016	The Claimant states that they tried to call the other party one more time. The Claimant expresses once more their disappointment because they are awaiting an answer since February 2016 and they "cannot be patient anymore". The Claimant asks the Other Party to contact them and leaves phone number and email. The Claimant states that they have reviewed the SIEF agreement and they would like to proceed urgently with the registration.
26.	14/10/2016	The Claimant informs the Other Party that if they do not receive an answer by 19/10/2016, they will launch a data sharing dispute.

Annex III: THE LIST OF STUDIES SUBJECT TO THE PERMISSION TO REFER GRANTED BY ECHA

Scope of the dispute: All studies in tonnage band [redacted]

Scope of permission to refer: [redacted] **studies in tonnage band** [redacted]

List of studies ECHA grants you permission to refer

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

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

Annex IV: COPIES OF THE (ROBUST) STUDY SUMMARIES

ANNEX V: THE INSTRUCTIONS ON HOW TO SUBMIT YOUR REGISTRATION DOSSIER AFTER DISPUTE PROCEDURE

Following the decision by ECHA on your data-sharing dispute, you have been granted:

- the permission to refer to the [redacted] (along with the corresponding study summaries);
- the token to access an existing joint submission for the substance.

I. Instructions on how to prepare your dossier in IUCLID

In order to ensure that your dossier is processed correctly, you have to enter certain information in the dossier header as well as in the individual endpoint study records.

1. How to fill in the individual endpoint study records

Figure 1.1: In the 'Administrative data' section of each endpoint study record for which you received the permission to refer:

a) In the field 'Endpoint', indicate the endpoint for which you received the permission to refer
b) In the field 'Type of information' select 'other:'
c) In the adjacent free text field insert the text "Data sharing dispute"
d) In the field 'Adequacy of study' select 'key study' from the pick-list

Figure 1.1: Section 'Administrative data'

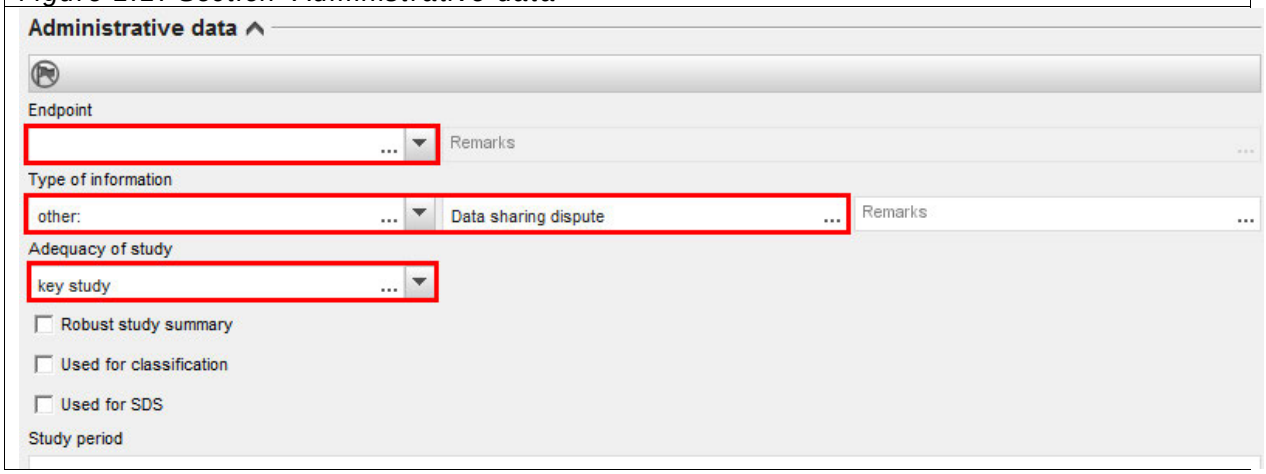


Figure 1.2: In the 'Data source' section of each endpoint study record for which you received the permission to refer:

a) In the field 'Reference', insert the literature reference of the provided study summary for which you received the permission to refer. To this end, click on 'Add' and at the bottom of the opening dialogue window, select 'New' and insert the information as provided to you.
b) In the field 'Data access': Select 'data submitter has permission to refer' from the pick-list.
c) In the adjacent free text field fill in as justification "Permission to refer granted by ECHA: [redacted]

Figure 1.2: Section 'Data source'

Remaining sections: Use the study summary information provided to you to fill in the sections:

- Materials and methods
- Test materials
- Result and discussion
- Overall remarks, attachments
- Applicant's summary and conclusion

2. How to create an opt-out dossier

By provision of the 'one substance one registration' principle, all registrants that register the same substance must submit their dossiers through a joint registration. This also applies to registrants who by means of a data sharing dispute decision are granted permission to refer to study information. In this case, the registrant must join the joint registration by means of a token provided by ECHA (see chapter II of this Annex), and submit a joint submission member dossier, opting out for the jointly submitted information in sections 2.1 and 4-7.

Figure 2.1: To create an opt-out dossier, you need to follow these steps:

a) Include all the relevant information to be submitted at the selected tonnage band in sections 2.1 and 4-7 of IUCLID 6.
b) Create a new record in section 14 – *Opt out information for REACH registration*, and create a block under 'Data selected for opt-out'.
c) Link all the documents in section 2.1 and sections 4-7 in the table 'Documents' of the created block. Enter the following explanation for the opt-out in the 'Justification' field: "Data sharing dispute according to Article 30(3)".
d) Create the dossier using the appropriate dossier template for a REACH registration as joint submission member. All the documents that are linked in section 14 will be included in the dossier as opted out information.

Figure 2.1: Section 14 – Opt-out information for REACH registration'

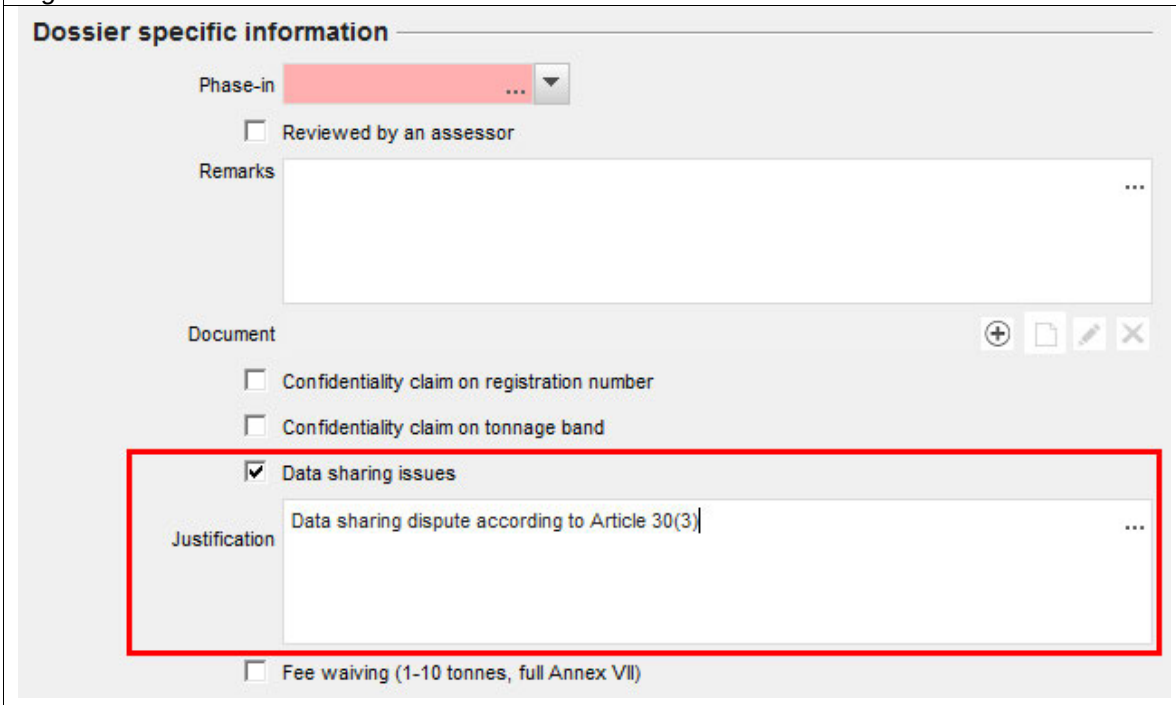
ECHA will verify that joint submission member registrations which have received the token following a data sharing dispute, (i) have indicated in the dossier header that the registration has undergone a data sharing dispute, and (ii) that the dossier contains the full information as corresponds to the Annex at which the registration is submitted.

3. How to fill in the dossier header

Figure 3.1: Once you have entered the information for the endpoint study records for which you were granted permission to refer, as well as for the other endpoints (outside of the scope of Article 30(3)) and the other sections of your registration dossier, proceed with creating the dossier. In the dossier header, in addition to the details on the submission (tonnage band, phase-in status etc.), you need to indicate the following:

a) [redacted]

Figure 3.1: How to fill in the dossier header



Notes:

- In addition to the provided study summary information; for the other endpoints (outside of the scope of Article 30(3)) and the other sections of your registration dossier, you must fill in the information as for any registration.
- We recommended you to use the IUCLID Validation Assistant to check the completeness of your dossier before submitting it to ECHA. Any failure reported by the Validation assistant on business rules or completeness check rules must be corrected to achieve a successful submission.
- Following the data sharing dispute, you may need time to generate or obtain any information that ECHA is not entitled to grant you permission to refer to. However, this information must be provided by the second (extended) TCC deadline at the latest. If you have followed these instructions, ECHA can grant you a **reasonable** extended deadline to compile and submit the necessary information.

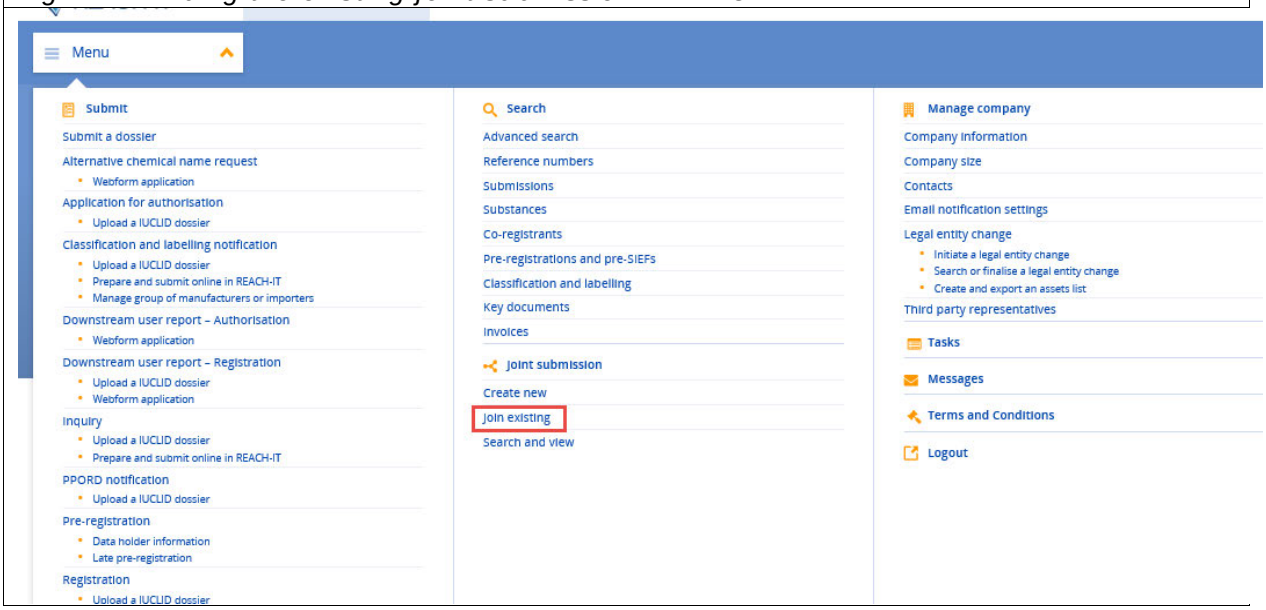
II. Instructions on how to submit in REACH-IT your opt-out dossier as member of the existing joint submission

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: [redacted]

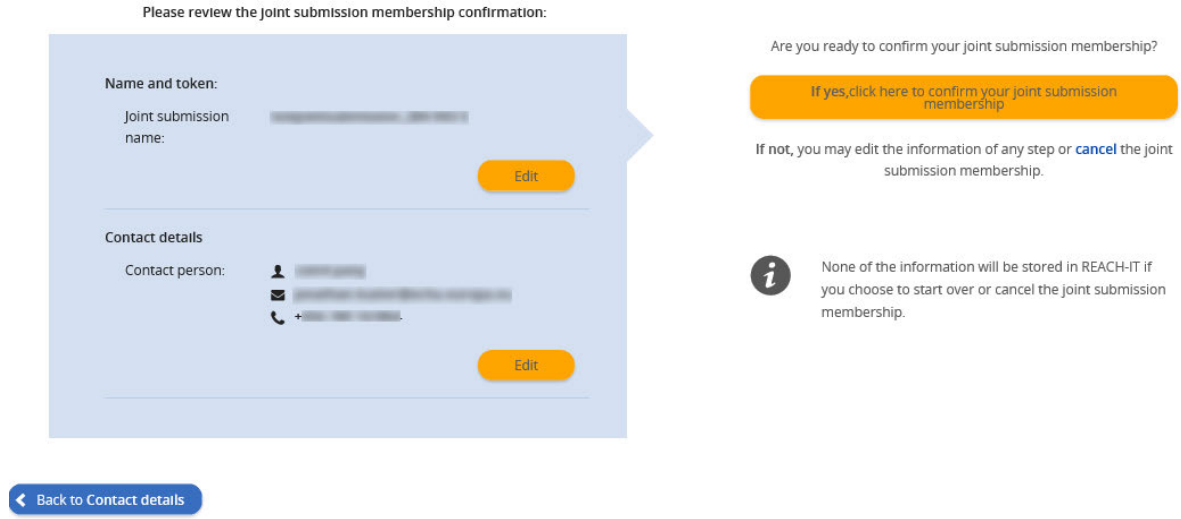
3. Update your contact details, if needed

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



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.