[redacted]

Helsinki, 18 May 2017

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

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

DECISION ON A DISPUTE

a) Decision

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

ECHA grants you access to the joint submission of the above-mentioned substance.

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 are provided in Annex III.

[1] Regulation (EC) N° 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, *OJ* L 396, 30.12.2006, p.1, as last amended.

[2] Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), *OJ* L 3, 6.1.2016, p.41.

[redacted]

b) Procedural history

On 27 February 2017, you ('the Claimant') submitted a claim concerning the failure to reach an agreement on the access to the joint submission with [redacted] ('the Other Party') as well as the related documentary evidence to ECHA. To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA also requested the Other Party to provide documentary evidence regarding the negotiations. The Other Party submitted the documentary evidence on 17 March 2017.

a) 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.

b) 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[3]

Director of Registration

[3] As this is an electronic document, it is not physically signed. This decision has been approved according to the ECHA's internal decision-approval process.

[redacted]

Annex I: REASONS OF THE DECISION

According to Article 11 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) 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

SIEF communication started on 20 November 2010 when the Other Party proposed themselves as lead registrant for the substance and stated their intention to register the substance [redacted] in the [redacted] tonnage band[4].

On 30 September 2011, the Claimant initiated the data sharing negotiations and informed that they owned data as well as that they disagreed with the Other Party being the lead registrant[5]. The Claimant also expressed their interest to register by [redacted] for [redacted] tpa.[6]

From 2011 onwards, the Claimant repeatedly informed the Other Party[7] that they owned data and that they would be willing to share their data with the Other Party. However, while the Other Party requested further information on the Claimant's available data and its costs in early 2013,[8] they proceeded thereafter with submitting the joint submission, after having conducted '*some of those studies*' stating that this was due to the '*absence of the information* [redacted]'[9].

After the submission of the joint submission by the Other Party, the parties discussed the

[4] See document Ref. no. 1
[5] See document Ref. no. 7
[6] See document Ref. no. 10
[7] See document Ref. no. 10, 15, 16, 17
[8] See document Ref. no. 18
[9] See document Ref. no 28

submitted information and whether the Claimant's studies could be included, too. The parties discussed the option of the Claimant becoming member of the joint submission by relying on the information already submitted in the joint submission, which however could include the Claimant's own data, too. As an alternative option, the parties also discussed the possibility of the Claimant submitting their own data separately while remaining part of the joint submission (i.e. opt-out).[10]

The Claimant provided information on their data as well as on its costs, as requested by the Other Party[11]. Further, between January 2013 and October 2016, the Claimant asked repeatedly for cost information about the data submitted in the joint submission as well as the costs for joining the joint submission[12]. The Other Party however never provided this information.

The Claimant especially sought access to the Other Party's OECD [redacted] study, which, according to the Other Party's statement, was ongoing at the time of the negotiations[13]. While the Other Party in general agreed to give the Claimant access to this study, either with a Letter of Access to the whole dossier, or alternatively, only to that study, with the Claimant submitting their own data (opt-out) for all other endpoints[14], the Other Party did not provide any relevant cost information.

With their dispute claim, the Claimant requested the Agency to grant them access to the aforementioned OECD [redacted] study as well as to the joint submission. ECHA notes that this study had not been submitted by the Other Party at the time the dispute was filed.

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. Sharing information on the cost calculation in accordance with the parties' duties under REACH and the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data sharing is therefore essential for successful data-sharing negotiations.

In particular, under Article 2 of the Commission Implementing Regulation, a potential registrant has the right to receive '*the itemisation of the data to be shared including, the cost of each data item, a description indicating the information requirements in Regulation (EC) No 1907/2006 to which each cost corresponds and a justification of how the data to be shared satisfies the information requirement'.* It also requires that the potential registrants receive upon request '*the itemisation and justification of any cost of creating and managing the data sharing agreement and the joint submission of information*', i.e. the '*administrative costs'*.

Thus, a potential registrant, upon their request, must receive from the existing registrants a meaningful cost break down in relation to the data submitted in the joint submission. This cost breakdown must link the relevant cost items with the data requirements and provide a justification for each cost item. The cost breakdown must also include information and relevant justification regarding the related administrative costs, including such costs related to joining the joint submission. The information provided must be detailed enough to allow

[10] See document Ref. no. 25
[11] See document Ref. no. 22, 25, 26
[12] See document Ref. no 15, 27, 29, 30, 32 and 34
[13] See document Ref. no. 33
[14] See document Ref. no. 33 and 35.

the potential registrant to assess the specific need for each study, its respective cost and the justification and relevance of the requested administrative costs for the potential registrant's registration. The Commission Implementing Regulation specifies further that this cost itemisation must be provided to the potential registrant without undue delay.

The Claimant informed the Other Party about the availability of own data already in 2011[15]. In 2013, the Claimant provided detailed information about the costs and reliability of their studies[16], as requested by the Other Party, which could allow the parties to share available data and thereby avoid unnecessary testing. This shows the Claimant's efforts to reach a fair, transparent and non-discriminatory agreement on the sharing of their own data that could be of relevance to the joint submission for the substance.

The Claimant also requested numerous times details on the sharing of the costs of the data that the Other Party submitted in the joint submission, including the costs associated with the OECD [redacted] study, which was ongoing at the time of the parties' negotiations. They also requested repeatedly the costs of joining the joint submission[17]. The Claimant emphasised the necessity of receiving the information about the detailed cost calculation during the entire negotiation process to enable the parties to reach a fair, transparent and non-discriminatory agreement as required by REACH and the Commission Implementing Regulation.

Despite the Claimant's aforementioned numerous requests for a transparent itemisation of the data and administrative costs, including the costs associated with the requested OECD [redacted] study and with joining the joint submission, the cost break down was not provided by the Other Party until the date the dispute was filed.

Without this information, however, the Claimant was not in a position to have full knowledge on the costs of the data submitted in the joint submission, including in relation to the ongoing OECD [redacted] study, nor on the related administrative costs. This is in spite of the aforementioned obligation of the existing registrants under REACH and the Commission Implementing Regulation to provide a potential registrant without undue delay with information on the data and its costs as well the costs associated with the administration of the joint submission.

Conclusion

Based on the above, ECHA considers that the Claimant made every effort to reach a fair, transparent and non-discriminatory agreement with the Other Party on the sharing of the data and the joint submission of information. On the other hand, by failing to provide a transparent itemisation of the costs of the data submitted in the joint submission and the related administrative costs, the Other Party did not fulfil their respective obligations under REACH and the Commission Implementing Regulation. Therefore, the Other Party did not make every effort to reach a fair, transparent and non-discriminatory agreement on data sharing and the joint submission of information with the Claimant.

[15] See document Ref. no. 7
[16] See document Ref. no. 15, 22, 25,
[17] See document Ref. no. 15, 27, 29, 30, 32

[redacted]

Observations

ECHA notes that, when submitting the dispute claim to the Agency, the Claimant also requested ECHA to grant them access to the OECD [redacted] study, which, according to the Other Party, was ongoing at that time.

Under Article 30(3) of REACH, for pre-registered phase in substances, ECHA can grant access to studies involving vertebrate animals that are '*available*' in the SIEF. In the case at hand, however, the aforementioned OECD [redacted] study was ongoing at the time of the parties' negotiations, i.e. it was not yet '*available*' in the SIEF.

ECHA notes that, for pre-registered phase-in substances, in relation to relevant studies involving tests that are not available within the SIEF, Article 30(2) of REACH applies. Based on this Article, if a disagreement exists on who is to carry out the test on behalf of the other SIEF participants, the Agency shall specify which registrant shall perform the test. In such case, all SIEF participants who require the study shall share the costs and will have the right to receive the full study report within two weeks following payment to the participant that carried out the study.

Accordingly, if the Claimant wishes to benefit from the dispute resolution mechanism provided for in Article 30(2) REACH in relation to the requested OECD [redacted] study, they may submit a relevant request to ECHA using the web-form available at https://comments.echa.europa.eu/comments_cms/article302.aspx .

Further information can be found in the Guidance on data sharing, Chapter 3.4.1 'Data-sharing disputes according to Article 30(2)', available at https://echa.europa.eu/guidance-documents/guidance-on-reach.

[redacted]

Annex II: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

CHRONOLOGY TABLE		
Reference number	**Submission date**	**Article**
[redacted]	[redacted]	30(3)

Ref. no.	Date	Content	Remark
1.	20/11/2010	The Other Party proposes itself as lead registrant and sends SIEF survey including survey on available data, with deadline 06/12/2010	Not provided by the Other Party
2.	06/12/2010	The Other party sends to the entire SIEF a reminder about their email from 20/11/2010, and proposes themselves as lead registrant. Deadline to reply is 09/12/2010	Not provided by the Other Party
3.	02/02/2011	The Other party writes to the entire SIEF with the results of the survey: they are nominated as lead registrant. Data gap analysis is in process and results will be communicated to potential participants.	Not provided by the Other Party
4.	01/04/2011	The Other Party informs they are nominated as lead registrant and that ECHA was informed. Preliminary Road Map for registration is attached. Substance sameness will be circulated later. Request to inform about data available for the substance within 30 days; no response means no data available.	Not provided by the Other Party
5.	12/08/2011	General SIEF kick-off survey by a third party.	Not provided by the Other Party
6.	02/09/2011	Other party to entire SIEF to inform about intention to register the substance [redacted] t/a before the	Not provided by

Ref. no.	Date	Content	Remark
		deadline [redacted]. SIEF agreement is finalised.	the Other Party
7.	30/09/2011	Claimant to other party to inform about disagreement on the lead registrant role, asking the Other Party to *'retreat from the role SFF/lead registrant'*. The claimant informed also that they are data owner.	Not provided by the Other Party
8.	11/10/2011	Email from third party (part of the SIEF) to the entire SIEF to disagree with the Other Party as lead registrant. They claim they disagreed already in December 2010 but their and other companies' disagreement was ignored by the Other Party. They assume that the lead registrant *'offers SIEF management services for financial purposes'*. They request the lead registrant to reveal which company they are representing or to resign from the status as LR and to inform ECHA, deadline 25/10/2011.	Not provided by the Other Party
9.	13/10/2011	The Other Party states they are acting as OR for [redacted] and as OR for [redacted] other companies, stating that they took the lead registrant role as a consequence of their experience with *'exorbitant fees, including huge amount as administrative fee'* during previous registrations.	Not provided by the Other Party
10.	19/10/2011	Claimant informs other party that they intend to register the substance by [redacted] and that they have data available.	Not provided by the Other Party
11.	04/11/2011	Other party informed that no SIEF member has indicated that they were data holders and reminds data holders to identify themselves by 25/11/2011. They will initiate testing if no SIEF member replies. They confirm their plans of registering [redacted] t/a by [redacted].	Not provided by the Other Party
12.	10/11/2011	Other party to entire SIEF to update on the registration preparation. Finalisation of data gap analysis expected by December 2011.	Not provided by the Other Party
13.	17/05/2012	Other party to entire SIEF updating about the SIEF activities and requesting to inform about uses for the CSR by 31/05/2012.	Not provided by the Other Party
14.	14/12/2012	Other party to entire SIEF about update of the registration. Information that LoA cost will be *'shortly*	Not provided by

Ref. no.	Date	Content	Remark
		available'.	the Other Party
15.	09/01/2013	Claimant informs other party about intention to register by [redacted] and asks about cost sharing decision. Claimant also provides details on available data as well as Other Party's SIEF questionnaire of 06/12/2010.	Not provided by the Other Party
16.	10/01/2013	The claimant resends to other party the same email as 09/01/2013	
17.	21/01/2013	The claimant sends a reminder to other party asking about confirmation of their email dated 10/01/2013.	
18.	21/01/2013	Other party requests claimant to sign confidentiality agreement to evaluate the data available, and to get information about cost details of available data to make the decision.	
19.	28/02/2013	Claimant sends confidentiality agreement by email and informs that two original documents have been sent by courier.	Not provided by the Other Party
20.	11/03/2013	Other party informs claimant that they have received the confidentiality agreement and requests the cost details for the available endpoints.	Not provided by the Other Party
21.	12/03/2013	The claimant requests to receive the signed confidentiality agreement before providing the cost details for the available endpoints. The claimant asks about the intended tonnage band which the other party will register and if they will register according to Art.10 or Art.18.	Not provided by the Other Party
22.	22/03/2013	The claimant informs that the countersigned confidentiality agreement had been received, and provides the requested information on study costs per endpoint for the data they own.	
23.	04/05/2013	The other party informs the SIEF that they have registered the substance and that the Joint Submission is open for SIEF members.	Not provided by the Other Party
24.	02/12/2013	The other party ask about dates and GLP status of studies including Klimisch rating, as the study	

Ref. no.	Date	Content	Remark
		reports were not offered earlier by the claimant for review.	
25.	18/12/2013	The claimant sends the study list including Klimisch factor and GLP status. The claimant remarks the other party's dossier consists mostly of QSARs and weight of evidence, while their own studies are '*GLP compliant and reliable without restriction*'. The claimant states they will not compensate those endpoints covered with QSAR or weight of evidence, for which studies exist, and will scientifically evaluate those QSARs or weight of evidence arguments for which no studies exist. Claimant will provide robust study in IUCLID format, subject to an administrative charge. The claimant will also prepare a data gap analysis for [redacted] tonnage band by January 2014.	Not provided by the Other Party
26.	30/01/2014	The claimant sends their data gap analysis which includes proposal to perform tests. They propose to discuss the proposal and agree within the joint submission.	Not provided by the Other Party
27.	08/12/2015	The claimant sends a reminder of their emails dated 18/12/2013 and 30/01/2014 and summarises the previous negotiations. They ask if SIEF agreement and LoA are available and how to proceed with the participation in the Joint Submission, requesting a reply by 08/01/2016.	
28.	05/01/2016	The other party writes that they have performed some studies in the absence of information on the data owned by the claimant before [redacted]. They inform they might include some of these studies in the lead dossier, and request the claimant to send substance sameness information and use profile for the substance.	
29.	26/01/2016	The claimant writes that the other party was repeatedly informed of the availability of data from the claimant already since 2011 They write that according to ECHA's dissemination portal, the lead dossier does not contain Annex [redacted] and [redacted] data and ignores existing vertebrate studies, resulting in the repetition of animal studies in 2013 and 2014 by the Other Party. The claimant states that they will fill the joint registration form only after knowing the price to participate in the Joint Submission for the substance in the [redacted] t/a and request a response by 02/02/2016	

[redacted]

Ref. no.	Date	Content	Remark
30.	04/02/2016	The claimant sends a reminder about the email from 26/01/2016. The claimant indicates that the case will be presented to ECHA if the other party does not reply by 11/02/2016	Not provided by the Other Party
31.	05/02/2016	The other party informs that such *'detailed request'* takes up to 15 working days to answer and promises to come back with the final list of studies by the end of the following week. (12/02/2016)	
32.	29/07/2016	The claimant expresses again their aim to register jointly at the [redacted] t/a. They inform about a teleconference held with ECHA on 06/06/2016 on this matter. The claimant states two possible scenarios: Either both parties reach an agreement, including on a possible opt-out, or the claimant would file a data sharing dispute. The claimant requests the other party to provide an itemisation of registration costs and proof of the study costs '*without undue delay*', as required by the Implementing Regulation. The claimant expresses their interest in reaching an agreement on the inclusion of own data in the lead registration dossier and the cost sharing for the jointly submitted data, and requests the other party to make a proposal how the data owned by the claimant would be included in the lead dossier. They also request clarification regarding an OECD [redacted] or [redacted] study, asking whether the other party has this study available, or intends to perform this study or any other vertebrate studies. The claimant requests an answer by 31/08/2016, otherwise a data sharing dispute would be filed.	
33.	03/08/2016	The other party informs that they are performing an OECD [redacted] study and they are expecting the results by 2016. They propose to share the costs and the related administrative costs, and informs that the claimant can join the registration after the payment of the compensation for that study as well as administrative costs, and opt out for the data already available.	
34.	28/10/2016	The claimant requests an answer to all questions from the email dated 29/07/2016 by 11/11/2016. The claimant informs that they will otherwise submit a data sharing dispute	
35.	29/10/2016	The other party states that they had offered the claimant two options: to opt-out for their own data and to share the OECD [redacted] study and grant a token to the joint submission.	