[redacted]

Helsinki, 16 June 2017

The Claimant

[redacted]

represented by

[redacted]

Copy to:
The Other Party

[redacted]

Copy to the lead registrant:

[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[1] you requested from the Existing Registrants of the above-mentioned substance, represented by [redacted] Consortium.

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. The factual background of the dispute is

[1] Refer to Annex III and IV for a list of the studies

[redacted]

described 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 21 March 2017, you ('the Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with [redacted] Consortium ('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 6 April 2017.

c) Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to the Board of Appeal of ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/web/guest/regulations/appeals.

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[2]

Director of Registration

[2] 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

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.

Summary of factual background

The Claimant initiated the negotiations on 14 April 2016, requesting a price quotation for a Letter of Access ('LoA') for all tonnage bands[3].

In their reply, the Other Party informed that they '*are currently working on the implementation of the new regulation on data sharing*' and that the new, updated calculation '*should be ready by Q2 or Q3 2016*'[4]. In addition, the Other Party asked whether the Claimant has a specific registration timeline[5].

On 25 July 2016, the Claimant sent a reminder asking the Other Party to provide the price of the LoA '*by the end of this week*' or give an exact time period by when it would be provided[6]. In their reply, the Other Party wrote that they intended to make a SIEF survey to be able to estimate the number of registrants, and indicated that the LoA cost '*should be ready by Q3 2016*'[7].

The Claimant repeated their request on 1 September 2016 and pointed out that they would consider a lack of reply on the price of the LoA '*as a kind of competition conduct*'[8]. In their reply, the Other Party announced a '*delay*', due to a SIEF survey[9] and discussions within the Consortium, as well as due to the adaption of their cost model to the requirements of the Commission Implementing Regulation. They informed that the LoA price and cost itemisation would be communicated in Q1 2017. At the same time, they indicated that the Claimant still had sufficient time to register [redacted] and mentioned the possibility of a '*temporary solution*' in case an immediate registration would be needed[10].

In the following, the Claimant informed of their intent to register by the end of 2016 and gave a deadline to provide the LoA price by 31 October 2016, announcing that they would file a dispute otherwise[11]. The Claimant then extended this deadline to 15 November

[3] See references no. 1, 4
[4] See references no. 5, 6
[5] See reference no. 6
[6] See reference no 7
[7] See reference no. 8
[8] See reference no. 9
[9] See references no. 10
[10] See reference no. 10
[11] See reference no. 11

[redacted]

2016[12], and later announced that they would '*definitely*' want to register in Q1 2017[13]. With their email of 16 January 2017, the Claimant gave a final deadline of 10 February 2017 for the Other Party to provide the requested LoA price and cost itemisation[14]. In turn, the Other Party repeatedly stated that the LoA cost would be ready in Q1 2017[15].

While expressing their wish to register urgently, the Claimant underlined that, it '*is not the duty of a SIEF-Manager to decide for a co-registrant when he has to register his substance*'[16] and referred to the '*competitive disadvantage*' of being prevented from using '[redacted]'[17]. However, the Other Party stated that [redacted][18]. They further stated that the temporary solution was an option '*in case an immediate registration is legally required*'[19]. They also stated that they did not see any '*competition issue because [the Claimant]* [redacted]'[20].

The Claimant filed the dispute on 21 March 2017.

Assessment

In accordance with Article 30 REACH and Articles 2 and 4 of the Commission Implementing Regulation, a potential registrant has the right to receive an itemisation of the costs related to data and administration. Such information is crucial to enable meaningful data sharing negotiations, as a potential registrant is not in a position to objectively assess and understand the data and the corresponding costs otherwise. It enables the potential registrant to assess whether the requested compensation is fair, transparent and non-discriminatory, as required by REACH and the Commission Implementing Regulation, as well as to assess the relevance of the jointly submitted data.

Further, according to Article 2(2) of the Commission Implementing Regulation, upon request of a potential registrant, the existing registrants need to provide proof of the cost of any study and '*make every effort to provide itemisation of all other relevant costs, including administrative costs and study costs*' '*without undue delay*'. In other words, the itemisation of costs must be provided to the potential registrants as soon as possible after they requested it. Therefore, any delays need to be duly justified. Moreover, a delay cannot in any case be justified if it results in obstructing potential registrants that have contacted the data owner in a timely manner from registering.

The Claimant repeatedly requested the cost itemisation, in line with their rights under the Commission Implementing Regulation. They accepted the initial timeline proposed by the Other Party, sent repeatedly reminders and set new deadlines when the Other Party did not provide the requested information within the initial timeline.

On the other hand, the Other Party did not provide any cost itemisation by the time the dispute was filed, i.e., over 10 months after the initial request from the Claimant. As

[12] See references no. 12, 14
[13] See reference no. 15
[14] See reference no. 17
[15] See references no. 10, 16, 18
[16] See reference no. 14
[17] See reference no. 17
[18] See references no. 10, 13
[19] See reference no. 16; note that the Other Party also mentions that '*in case [the Claimant has] an immediate registration duty, a temporary solution will be found*' (reference no. 18)
[20] See reference no. 18

[redacted]

explained above, the Other Party is under the obligation to provide a cost itemisation upon request without undue delay. The Other Party attempted to explain why they were not able to provide the cost itemisation upon the first request as well as for the further delays, i.e., discussions within the Consortium and the SIEF as well as adapting their cost model to the requirements of the Commission Implementing Regulation.

First, ECHA notes that registrants are free to organise themselves in any form they find suitable. Consequently, co-registrants are free to establish a consortium to coordinate their registration. The internal organisation of such a consortium and its communication with the other SIEF members is in the responsibility of its members. Their organisational decision must not be to the detriment of the rights of potential registrants. The existing registrants need to accommodate requests for data sharing and access to the joint submission, including the provision of a meaningful cost itemisation in line with the requirements of the Commission Implementing Regulation, '*without undue delay*'. Against this backdrop, a delay such as the one encountered in the present case (of over 10 months) cannot be justified by the way the existing registrants decided to organise themselves.

Second, ECHA reminds the parties that the principles of fairness, of non-discrimination, and, most importantly in the present dispute, of transparency in data-sharing negotiations existed prior to the Commission Implementing Regulation or any updated Guidance document. The adaptations of the cost model to the requirements of the Commission Implementing Regulation and the clarifications provided by the new Guidance on data sharing cannot justify that the Other Party did not provide any cost estimate nor any information on the data by the time the dispute was filed.

Therefore, it cannot be considered that the Other Party acted '*without undue delay*'. Thus, the Other Party did not make every effort in the negotiations.

Further, the Claimant expressed the wish to register as soon as possible and provided explanations for their urgency (i.e. [redacted][21]). ECHA notes that the Other Party mentioned a temporary solution in case of '*immediate registration duty*' while the cost itemisation was being finalised. However, the Other Party did not explain further the content of this offer, and repeatedly stated that there was no urgency in the case of the Claimant, [redacted]. The Claimant mentioned business reasons for their need to register [redacted]. However, the Other Party did not address these, but merely dismissed the urgency arguments raised by the Claimant. In this case, especially considering the duration of the negotiations, the Other Party would for example have been able either to finalise the itemisation or provide clarifications whether and how the Claimant could benefit from the '*temporary solution*'.

Conclusion

Based on the above, ECHA concludes that the Claimant made every effort to reach an agreement on data sharing and access to the joint submission in a fair, transparent and non-discriminatory way.

On the other hand, by not providing the requested cost itemisation without undue delay and by not accommodating the Claimant's request to register urgently, the Other Party breached

[21] See reference no. 11

[redacted]

their obligation to make every effort to reach a fair, transparent and non-discriminatory agreement.

Therefore, ECHA grants the Claimant a permission to refer to the information requested from the Existing Registrants, as listed in Annex III to the present decision.

Observations

ECHA reminds both parties that the outcome of a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would. Accordingly, ECHA strongly encourages the parties to continue their efforts to reach an agreement that will be satisfactory for both parties.

Furthermore, ECHA reminds the parties that they are still under the obligation to share data. While with the present decision ECHA only gives a permission to refer to studies involving tests on vertebrate animals, the obligation for a data owner to share data and for both parties to make every effort to reach a fair, transparent and non-discriminatory agreement also extends to non-vertebrate data. Further, according to Article 30(6) of REACH, a refusal by a data owner to share data (including non-vertebrate data) '*shall be penalised in accordance with Article 126*'.

[redacted]

Annex II: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

Ref. no.	Date	Content	Remark
1.	14/04/2016	The Claimant initiates the negotiations and asks the Lead Registrant to provide the price of the Letter of access (LoA) for all tonnage bands.	
2.	14/04/2016	The Lead Registrant informs the Claimant that the registration of the substance in question is done within a consortium and that the consortium manager ('Other Party') will provide all the information about purchasing a LoA.	
3.	14/04/2016	The Claimant acknowledges receipt of communication under ref.2	Provided only by the Claimant
4.	14/04/2016	The Claimant asks the Other Party to provide the price of the Letter of access (LoA) for all tonnage bands.	
5.	15/04/2016	The Other Party informs that they '*are currently working on the implementation of the new regulation on data sharing*'. The new calculation '*should be ready by Q2 or Q3 2016*'. SIEF will be informed.	
6.	15/04/2016	The Other Party communicates that they will share the prices for the LoA as soon as updated version is available and asks the Claimant if they have a specific timeline for the registration of the substance.	
7.	25/07/2016	The Claimant reminds that the Other Party would provide the LoA price by Q2 or Q3 2016 and asks the Other Party to provide the price by end of the week (29 July 2016) or give the exact time period in which it will be provided.	

[redacted]

Ref. no.	Date	Content	Remark
8.	26/07/2016	The Other Party informs that '*the new calculation for the LoA should be ready by Q3 2016*' taking into account the outcome of a survey that will assess the number of co-registrants within SIEF.	
9.	1/09/2016	The Claimant reminds that the Other Party wanted to provide the LoA costs by Q2 or Q3, and asks for '*the price or […] a time period in which this will be definitively communicated*'. They also make reference to the Implementing Regulation on data sharing and indicate that they will inform the authorities about possible competition issues in case they do not receive this information.	
10.	6/09/2016	The Other Party informs that there is '*a delay*'. They intend to make a SIEF survey to gather registration intentions, update the LoA calculation accordingly, and, following approval by the Consortium, will communicate the new LoA cost in Q1 2017. They underline that there is sufficient time [redacted], but that they would be willing to find a '*temporary solution*' in case an immediate registration is needed.	
11.	15/09/2016	The Claimant confirms their interest to register the substance [redacted] by the end of 2016. They request the LoA price by 31/10/2016 or otherwise they will file a dispute with ECHA.	
12.	28/10/2016	The Claimant asks for an update and informs that they will file a dispute if they don't get requested information by the extended deadline of 15/11/2016.	
13.	31/10/2016	The Other Party reminds that [redacted], and informs that they will '*soon*' give an update on the LoA prices for the 2018 registrants.	
14.	7/11/2016	The Claimant states that it '*is not the duty of a SIEF-Manager to decide for a co-registrant when he has to register his substance*'. They repeat their request for an update on the LoA price and inform that they will file a dispute if they don't get required information by 15/11/2016.	

[redacted]

Ref. no.	Date	Content	Remark
15.	18/11/2016	The Claimant informs that they '*would like definitively to register the substances in the first quartal (Q1) of 2017*' and repeat their request for the LoA cost.	
16.	29/11/2016	The Other Party informs the SIEF that work on a cost itemisation as required by the Commission Implementing Regulation is ongoing, but that an updated cost calculation will only be available in 2017. Registrants can buy LoA's under the old terms where available, but generally are asked to wait until 2017 or, '*in case an immediate registration is legally required*', make use of a '*temporary solution*'.	
17.	16/01/2017	The Claimant repeats their request and asks for an itemisation of the LoA cost by 10/02/2017, and informs that they will otherwise file a dispute with ECHA and file a '*law suit for the violation of European competitive law*' due to the '*competitive disadvantage*' of being prevented from using [redacted]'. They also repeat that it is their right to decide when to register [redacted].	
18.	17/01/2017	The Other Party states that the '*position of the consortium related to the availability of LoAs is very well known*', and that potential registrants will be informed as soon as the LoA prices are available. They state that '*there is no competition issue because* [redacted]*)*' and repeat '*that in case you have an immediate registration duty, a temporary solution will be found*'.	