[redacted]

Helsinki, 29 June 2017

The Claimant

[redacted]

Represented by

[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 does not grant you the permission to refer to the information you requested from the Existing Registrant, [redacted], of the above-mentioned substance.

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

b. Procedural history

On 31 March 2017, 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

[redacted]

provide documentary evidence regarding the negotiations. The Other Party submitted the documentary evidence on 25 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.

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.

[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.

According to Article 11 of the REACH Regulation, all registrants of the same substance are part of the same registration under REACH ('joint submission of data'). Further, Article 3(1) of the Commission Implementing Regulation requires ECHA to ensure that all registrants of the same substance are part of the same registration for the substance.

Article 3(3) of the Commission Implementing Regulation also confirms that a potential registrant may decide to invoke Articles 11(3) or 19(2) of REACH in order to submit separately all or part of the relevant information in Article 10(a) of REACH. Before doing so however, the potential registrant is required to ensure that he has complied with his obligations under Articles 26 or 29 of REACH and has ascertained that he is not required to share tests on vertebrate animals for the purposes of his registration.

In 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 terms of access to the joint submission and sharing of data in a fair, transparent and non-discriminatory way.

Summary of factual background

The Claimant started the negotiations on 2 March 2016, informing the Other Party that they would like to join the joint submission but intend to opt out for the information referred to in Article 10 (a) (iv), (vi), (vii) or (ix) of the REACH Regulation, invoking Article 11(3). The Claimant indicated that the opt out is justified by disagreement with the price of the LoA and with the selection of the jointly submitted information, stating that there was available '*free data of acceptable quality*'. In addition, with reference to the Commission Implementation Regulation (EU) 2016/9, the Claimant also requested a specification of the LoA costs '*to the remaining part of the "joint submission dossier"'* as well as a breakdown of the study and administrative costs.[2] At a later stage, they requested also a '*full specification'* of the LoA costs arguing that many of the endpoints *'are waived or fulfilled by the use of "read-across"'*.[3]

On 29 March 2016 the Other Party informed that before giving access to the joint submission they require i) specification of the information the Claimant requests access to ii) '*a description of the data which [the Claimant] consider[s] "free", "of acceptable quality" and "available"'* that would therefore justify the Claimant's opt-out and iii) an explanation as to how they have access or are in possession of such data. In addition, the Other Party pointed out that the Claimant had submitted an individual registration without a prior contact with the lead registrant and/or the SIEF members and that the Claimant did not explain why it considers the cost of the LoA too high.[4]

[2] See references no 1 and 3

[3] See reference no 3

[4] See reference no 2

[redacted]

On 29 June 2016 the Other Party provided the Claimant the with link to the LoA agreement and pointed out that, as the Lead Registrant, they are entitled to obtain information from any potential registrant '*to ensure that all participants to the joint submission are granted access to the jointly submitted information in a fair, transparent and non-discriminatory sharing of the costs for information'*. Therefore, they repeated their earlier request concerning the scope of the Claimant's request for data and the data to which the Claimant has access. Furthermore, the Other Party informed that the requested specification of the study and administrative costs would be ready by the end of July 2016.[5]

On 30 August 2016, the Other Party provided the specification of the study and administrative costs requested by the Claimant and repeated again their requests of 29 March and 29 June 2016.[6]

In their reply on 23 December 2016, the Claimant stated that they still find the costs very high and in particular, the expenses related to the LoA. Therefore, they requested additional information about the pricing of the studies and the reasons why the studies have been performed and justification for certain data costs.[7] This was also the last communication from the Claimant to the Other Party before they submitted the dispute to ECHA.

In their reply on 5 January 2017, the Other Party stressed that the Claimant never answered to their requests and as '*another gesture of goodwill'* provided the Claimant with the additional information to accommodate their request.[8]

The Claimant submitted the dispute on 31 March 2017.

Assessment

In accordance with Article 30 (1) of the REACH Regulation, *'the participant (s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way'.* Registrants who need information should enter into discussions in order to agree on the nature of data they are going to share and on the cost sharing approach.

Making every effort means that the parties need to provide answers to the questions that they receive from the other party. Conversely, a party that receives a reply to their question must consider this reply. In other words, making every effort means to address questions and answers in a constructive manner to enable the parties to find a common understanding on the data that needs to be shared and the terms of sharing the data in a fair, transparent and non-discriminatory manner.

At the outset, the Claimant stated an intention to opt out, but requested a full cost itemisation of the Letter of Access in line with their rights under the Commission Implementing Regulation. The Other Party provided the requested information as well as, upon request by the Claimant, additional clarification on the provided information. ECHA notes that this is in line with each parties' respective obligation to make every effort to reach a fair, transparent and non-discriminatory agreement; such information on the data and its costs is crucial for meaningful data sharing negotiations.

The Claimant repeatedly stated that they considered the costs too high and asked further clarification on a number of cost items. However, after having received an explanation to

[5] See reference no 4
[6] See reference no 5
[7] See reference no 6
[8] See reference no 7

[redacted]

their request for additional clarification from the Other Party in January 2017, the Claimant filed a dispute in March 2017 without challenging the information received and without prior notice to the Other Party.

Thus, the Other Party made every effort to find an agreement by providing answers to the Claimant's requests and by making enquiries of their own to understand the data needs of the Claimant. The Claimant could have accepted the Other Party's offer or explained any concerns regarding the offer on the basis of the explanations provided by the Other Party. However, the Claimant did not react to the information and explanations provided by the Other Party. Launching a data sharing dispute with ECHA should be done only as a last resort, i.e. only after all efforts to reach a negotiated agreement have been exhausted. The negotiations were progressing, and the Claimant could have made efforts to find an agreement on the basis of the information provided by the Other Party. By submitting a dispute before all efforts were exhausted, the Claimant failed to make every effort.

This finding is corroborated by the fact that the Claimant states that they wish to opt out, as costs are high and data is publicly available, but never informs the Other Party what data requirements they wish to opt out from and which data they wish to have access to. The Other Party asked the Claimant to provide a *'specification of the information from the joint submission which [the Claimant] require[s] access to'* as well as to provide information regarding the '*free data of acceptable quality*', which they intended to rely on for a potential opt out registration. The Claimant never answered to the Other Parties' requests. The obligation to make every effort to share available data applies to all co-registrants, i.e. not only to the Other Party but also to the Claimant. In particular, the Claimant must clarify which data they need to share for the purpose of registration.

Conclusion

Based on the above, ECHA concludes that the Claimant did not make every effort to reach an agreement on data sharing and access to the joint submission in a fair, transparent and non-discriminatory way, while the Other Party made every effort to find an agreement.

[redacted]

Annex II: ADVICE AND FURTHER OBSERVATIONS

ECHA stresses that both parties still share the common data-sharing obligation, and are therefore still required to make every effort to reach an agreement on the sharing of the information and of their related costs. Accordingly, ECHA strongly encourages the parties to continue their efforts to reach an agreement that will be satisfactory for both parties.

Furthermore, all registrants of the same substance need to be part of the same joint registration. All information submitted for a given substance, whether jointly or separately (opt-out), forms a set of data describing the hazardous properties of and the risks associated with the substance. Thus, to the extent that the information to be submitted separately (opt-out) defines the properties of the substance, it is of relevance to all registrants of that substance. Accordingly, a potential registrant wishing to submit such information separately can be therefore legitimately expected to share this information, upon request, with the other registrants of the substance.

[redacted]

Annex III: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

Ref. no.	Date	Content	Remark
1.	02/03/2016	The Claimant contacted the Other Party informing them that they would like to start negotiations with the intention to join the joint submission. The Claimant explained that the high price of the Letter of Access (LoA) combined with disagreement regarding the selection of information was the reason to submit an individual dossier. The Claimant referred to the fact that there is available '*free data of acceptable quality*'. The Claimant informed that they will opt out for the information in Article 10(a)(IV),(VI),(VII) or(IX). The Claimant asked the Other Party to specify the costs of LoA for '*the remaining part of the joint submission dossier*' with '*full specification of [Other Party's] costs*' according to the Commission Implementing Regulation (EU) 2016/9.	Provided by both parties
2.	29/03/2016	The Other Party informed that they are the Lead Registrant for the substance in question and they are welcoming new members to the joint submission. However before giving access to the joint submission the Other Party required the following information: • '*specification of the information from the joint submission*' which the Claimant requires access to • '*a description of the data which [Claimant] consider[s] to be free, of acceptable quality and available and therefore*' justifies Claimant's opt out • Explanation how the Claimant has access or is in possession of such data • The Other Party also pointed out that the Claimant had never before their email dated 2 March 2016 (i) responded to correspondence of the active members of the SIEF or (ii) participated to discussions within SIEF. In addition, the Claimant had submitted a separate registration for the substance without any contact or request to the lead registrant and without explanation why the Claimant considers the proposed LoA price excessive.	Provided by both parties

[redacted]

Ref. no.	Date	Content	Remark
3.	01/06/2016	The Claimant cited the Implementing Regulation (EU) 2016/9 and the fact that the potential registrant has right to request the itemization of the study and the administrative costs. The Claimant stated again that they are willing to be part of the joint submission dossier but they will opt out for the information referred in Article 10(a)(iv), (vi), (vii) or (ix). The Claimant stated as well, that many of the endpoints in the Lead dossier are waived or covered with read-across and therefore, the Claimant requires a full specification of the costs of the LoA. After the costs have been specified the Claimant is willing to proceed with negotiations for joining the joint submission. The Claimant further stated, with reference to the ECHA guidance on data sharing, that the legitimate possession of or permission to refer to the full study reports required by Article 10 of REACH could be considered as derived directly from intellectual property law. In this respect they argued that '*[c]opyright covers only the form or mode of expression, but facts and data themselves which are to be used to create a study summary for the purpose of the registration dossier are generally not copyright-protected*'.	Provided by both parties
4.	29/06/2017	The Other Party informed the Claimant that they are aware of the fact that ECHA will revoke the registration of the Claimant if the Claimant will not join the existing joint submission by 13 December2016. The Other Party informed that they shall make their best effort to ensure that the deadline can be met. The Other Party provided the link to the LoA agreement, which provides information about the rights and obligation of participants to the joint submission. Before proceeding the Other Party requested again the following information (as requested earlier on 29 March 2016): • Specification of the information from the joint submission to which the Claimant requires access. • List of existing studies on which the Claimant is relying • List of free available studies as stated in the Claimant's email dated 2 March 2016 • Legitimate possession of data	Provided by both parties

[redacted]

Ref. no.	Date	Content	Remark
		The Other Party informed that they are preparing full specification of administrative and data costs and this information will be delivered by the end of July 2016. Regarding the anticipation of the opt-out of the Claimant, the Other Party emphasized that as the Lead Registrant they are entitled to obtain information from any potential registrant, so that they can ensure that everyone in the joint submission is treated in fair, transparent and non-discriminatory way. Due to this reason the Other Party required the following information before proceeding with providing access to the joint submission. In respect to issue concerning the legitimate possession of data, the Other Party stated that the Claimant seemed to confuse two different things, i.e. (i) potential infringe of IP law, which is handled under IP law and (ii) the obligation under REACH to have legitimate possession or a right to refer to data. The Other Party pointed out that the legitimate possession in the context of REACH means that the registrant is required to hold a right to use the data for purpose of the registration.	
5.	30/08/2016	The Other Party sent a document containing the itemization of costs and reminded the Claimant to reply to the questions from the email dated 29 June 2016.	Provided by both parties
6.	23/12/2016	The Claimant asked for further clarification for certain items on the itemization of costs the Other Party sent on 30 August 2016.	Provided by both parties
7.	05/01/2017	The Other Party responded to the request for further clarification on the cost itemization and attached invoices to support the costs incurred. The Other Party again emphasized on the fact that the Claimant never replied the questions asked on 29 June 2016 and 30 August 2016 and before the Claimant is able to join the joint submission they need to answer the questions. The Other Party emphasized that as '*another gesture of goodwill*' they are able to provide the Claimant with additional information about the prizing of the studies and the reason why the studies have been performed.	Provided by both parties Attachments provided only by the Other Party