[redacted]

Helsinki, 26 April 2018

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

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

DECISION ON A DISPUTE RELATED TO THE ACCESS TO A JOINT SUBMISSION AND THE SHARING OF DATA

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 and access to the joint submission.

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 list of studies ECHA grants you permission to refer along with copies of (robust) study summaries can be found in Annex II and III, respectively. Instructions on how to submit your registration dossier are provided in Annex IV.

b) Procedural history

On 5 February 2018, 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. After the Other Party requested extension, ECHA granted them until 12 March 2018 to submit their evidence. The Other Party submitted the documentary evidence on 12 March 2018.

[redacted]

c) Appeal

Either party may appeal this decision to the Board of Appeal of ECHA within three months of its notification. The appeal must set out the grounds of appeal. If an appeal is submitted, this decision will be suspended. Further details including the appeal fee are set out at 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.

The present decision will be published in an anonymised version on ECHA's website[1].

Yours sincerely,

Christel Schilliger-Musset[2]

Director of Registration

[1] Available at https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach.

[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

A. Applicable law

Under Article 11 of the REACH Regulation 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')[3], all registrants of the same substance must be part of the same registration ('joint submission obligation') and must share data ('data sharing obligation') as well as the costs related to the joint submission.

When a dispute is submitted to ECHA pursuant to Article 30(3) of the REACH Regulation and Article 5 of the Commission Implementing Regulation, ECHA performs an assessment of the parties' efforts to reach an agreement. ECHA may grant a permission to refer to the relevant vertebrate studies and access to the joint submission, if the claimant has made every effort to find an agreement on the sharing of the data and the access to the joint submission, and the other party has failed to do so.

The obligation to make every effort to find an agreement that is fair, transparent and non-discriminatory is laid down in Article 30(1) of the REACH Regulation. It is further defined in Articles 2 and 4 of the Commission Implementing Regulation.

Making every effort means that the registrants must negotiate as constructively as possible and in good faith. They must make sure that the negotiations move forward in a timely manner, express their arguments and concerns, ask questions and reply to each other's arguments, concerns and questions. They must try to understand the other party's position and consider it in the negotiations. Making every effort also means that the parties need to be consistent in their negotiating strategy; they should raise their concerns in a timely manner and behave in a consistent and predictable manner as reliable negotiators. When they face a dissent on an aspect, the parties have to explore alternative routes and make suitable attempts to unblock the negotiations. As the potential and existing registrants themselves bear the obligation to make every effort to find an agreement, they need to exhaust all possible efforts before submitting a dispute to ECHA with the claim that negotiations have failed.

B. Factual background

On 12 June 2015[4], the Other Party informed the SIEF members of the successful submission of the registration for the substance and invited the SIEF members to contact the Other Party in case they wish to join the joint submission. The negotiations between the Claimant and the Other Party started on 12 May 2017 when the Claimant sent an email to the Other Party expressing their interest in joining the joint submission for the substance and asked the Substance Identity Profile ('SIP')[5]. The Claimant sent a reminder about their request on 31 May 2017 and asked for the costs for a Letter of Access ('LoA') for the different tonnage bands[6]. The Other Party responded on 5 June 2017 that their *'regulatory team has been informed and will be in touch'* in the following weeks[7].

In July 2017, the Claimant sent two reminders to the Other Party, expressing their urgency to register[8]. On 26 July 2017, the Other Party responded that their communication might be

[3] 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.

[4] Other Party, 12 June 2015

[5] Claimant, 12 May 2017

[6] Claimant, 31 May 2017

[7] Other Party, 5 June 2017

[8] Claimant, 3 July 2017, 26 July 2017

[redacted]

slow this time of the year and asked whether the Claimant has pre-registered the substance or filed an inquiry. The Claimant responded that they have pre-registered and explained further that they contacted the Other Party as they are the Lead Registrant for the substance in question[9]. The Other Party promised to check why they have not *'responded to* [the Claimant's] *enquiry and how* [the Other Party] *can provide the* [relevant] *information to allow for* [the Claimant's] *registration'*[10].

Between 2 August and 5 October 2017, the Claimant sent four reminders to the Other Party, indicating that they intend to register in the tonnage band [redacted] and asking for a reply.[11] The Other Party responded on 5 October 2017 that the Claimant's *'enquiry has been forwarded'* and they will *'get back at* [the Claimant] *very shortly'*[12]. The Claimant contacted the Other Party again on 23 October 2017 expressing their concerns [redacted] and asking the Other Party to provide a timeline for their requests; the SIP and the LoA cost, and again on 7 November 2017 pointing out that in absence of a reply they would have to contact ECHA. The Claimant sent another reminder on 28 November 2017.

On 29 November 2017, referring to a telephone conversation on the same day, the Other Party provided the SIP and explained that the LoA *'is currently being calculated and will be available in two weeks' time'*[13]. On 13 December 2017, the Claimant confirmed the substance sameness and asked for the LoA cost.[14] The Other Party responded on 3 January 2018, stating that the *'LoA calculation is finished and is now being checked so will be available shortly'*[15].

On 17 January 2018, the Claimant asked when the LoA cost will be available, to which the Other Party responded on 30 January 2018 that it is *'under review and* [the Other Party*] will provide an update soon'*[16]. On 5 February 2018, the Claimant responded stating that *'the absence of timeline to obtain the Letter of Access cost and duration the process to obtain information necessary to join the registration'* makes them doubt they will *'be able to join the registration in due time'*. The Claimant further stated that they want to ensure their compliance with the REACH Regulation even after the deadline, and thus will file a data-sharing dispute. [17]

The Claimant filed the dispute on 5 February 2018 requesting permission to refer to data in the tonnage band [redacted] tpa and access to the joint submission.

C. Assessment

As explained in section A., ECHA assesses the efforts made by the parties in the negotiations to reach a fair, transparent and non-discriminatory agreement on the sharing of data and the joint submission of information. In particular, making every effort requires that parties express clearly and transparently their needs and constraints, such as their registration schedule. It also means that the parties have to take into account the constraints expressed by their negotiating partner and respect the timelines they communicate to them.

The Claimant expressed clearly their interest to join the existing joint submission and repeatedly requested the Other Party to provide the LoA cost. Throughout the entire course

[9] Claimant, 27 July 2017
[10] Other Party, 27 July 2017
[11] Claimant, 2 August 2017, 8 and 25 September 2017, 5 October 2017
[12] Other Party, 5 October 2017
[13] Other Party, 29 November 2017
[14] Claimant, 13 December 2017
[15] Other Party, 3 January 2018
[16] Other Party, 30 January 2018
[17] Claimant, 5 February 2018

of the negotiations, the Claimant made efforts by replying in a timely manner and by sending several reminders when the Other Party did not respond to their request. In addition, the Claimant communicated early on in the negotiations the wish to register as soon as possible. They expressed that, due to the lack of reply by the Other Party, they were *'concerned'* whether they would be able to register on time their substance given the fast approaching registration deadline of May 2018. By doing so, the Claimant made efforts to clearly explain their situation and to make the negotiations progress.

In contrast, the Other Party ignored the Claimant's request and reminders several times, or responded by providing vague timelines for complying with the Claimant's requests such as *'shortly', 'very* shortly' or *'soon'*. In addition, the Other Party did not respect these communicated deadlines during the negotiations (even when they provided clearer timelines such as *'in two weeks time'*). The Other Party further did not provide any substantiated reasons for the delays. Despite the repeated requests by the Claimant for the LoA cost, the Other Party did not provide any information on the LoA cost during the negotiations, which lasted for almost nine months. Providing the LoA cost for the data to be shared and the access to the joint submission is the very starting point of the negotiations on data and cost sharing; in the absence of any information on the LoA cost, the negotiations on data and cost sharing between the Claimant and the Other Party could not start. Therefore, by not providing any information on the LoA cost and delaying the negotiations despite the Claimant's reminders on the urgency of their request, the Other Party failed to make effort to find an agreement on the sharing of data and access to the joint submission with the Claimant.

In light of the above, the Claimant could conclude that the discussions with the Other Party would not progress on time in view of their registration deadline and they filed the dispute to ECHA as a measure of last resort.

D. Conclusion

Based on the assessment above, ECHA concludes that the Claimant made every effort in order to reach a fair, transparent and non-discriminatory agreement on data and access to the joint submission, where the Other Party did not. Consequently, ECHA grants the Claimant access to the joint submission and permission to refer to the requested vertebrate data for the substance, specified in the Annex II of this decision, submitted by the Other Party.

E. Observations[18]

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'*.

[18] Please note that this section does not contain elements that ECHA took into consideration in its assessment of the parties' efforts in their negotiations. ECHA's assessment of the dispute is set out only in the section 'C. Assessment' of Annex I. The section 'E. Observations' aims only at providing further information that can be helpful for the parties in the future of their discussions on data sharing and joint submission obligations.