

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-Musset¹

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 FOR THE DECISION

Article 63(1) of the BPR requires prospective applicant(s) and data owner(s) to *'make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant'*. If no agreement can be reached, Article 63(3) of the BPR mandates ECHA, on request, to *'give the prospective applicant permission to refer to the requested tests or studies on vertebrates, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred'*. Accordingly, if ECHA finds that the prospective applicant complied with their obligation to make every effort to reach a fair, transparent and non-discriminatory agreement and paid the data owner a share of the costs incurred, the Agency shall grant the prospective applicant the permission to refer to the requested data.

For submissions of alternative suppliers relating to their inclusion on the Article 95 list, Article 95(3) of the BPR extends the scope of the right to refer under Article 63(3) of the BPR for active substances included in the Review Programme² *'to all toxicological, ecotoxicological and environmental fate and behaviour studies [...] including any such studies not involving tests on vertebrates'*.

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 sharing the studies and their related costs in a fair, transparent and non-discriminatory way.

Factual background

On 18 April 2018, the Claimant received a communication from the Agency as a reply to their request under Article 62(2) of the BPR. The communication included the names of two companies, one of them being the Other Party, as data submitters for the substance in question. For the Other Party, the communication indicated name and address of the company, and name and email address of one contact person.³

On 24 April 2018, the Claimant's consultant (hereinafter also referred to as the Claimant) sent an email to the Other Party and to the other data submitter using the email addresses received from ECHA. The email included a *'request for a Letter of Access for the purpose of inclusion in the Register of art. 95 of [the BPR] as supplier of [the substance in question]'*. The Claimant listed *'non-repeatable studies'* and requested access to them, and asked for a *'fee proposal by the 9th of May 2018'*.⁴

The same day, the Claimant received an automatic out of office reply from the Other Party, indicating that emails sent to that particular email address *'will not be read until [the contact person's] return'*. The email included a name of the contact person's substitute.⁵

On 22 May 2018, the Claimant sent a reminder to the Other Party, enclosing the same letter as to their original request, to the same email address as previously.⁶

² The work programme established by the Commission under Article 16 of Directive 98/8/EC for the assessment of existing active substances which is continued under Article 89(1) of the BPR, the detailed rules of which are set out in Commission Delegated Regulation (EU) No 1062/2014.

³ The Agency; 18 April 2018

⁴ The Claimant; 24 April 2018

⁵ The Other Party; 24 April 2018

⁶ The Claimant; 22 May 2018

On 7 June, the Claimant re-sent the request for a third time to the same email address as previously, indicating that in case the Other Party would not reply within a week, the Claimant would file a dispute to ECHA.⁷

On 6 July 2018, the Claimant re-sent the data-sharing request again to the Other Party and wrote that *'given the persistent lack of any reply to [their] requests – [the Claimant would be] obliged to submit a formal request to ECHA for the access to the studies on vertebrates owned by [the Other Party], pursuant to art. 63 BPR'* the following week. The email was again sent to the same email address with the Other Party as all previous emails.⁸

The Claimant lodged the present dispute at ECHA on 12 July 2018.

Assessment

Pursuant to Article 63 of the BPR, a prospective applicant and a data owner shall make every effort to reach an agreement on sharing of data that the prospective applicant has requested according to Article 62 of the same Regulation.

If no agreement has been reached on sharing the requested data and a dispute claim has been brought in front of the Agency, it shall grant the right to refer to the requested studies, *'provided that the prospective applicant demonstrates that every effort has been made to reach an agreement'* and that the prospective applicant has paid a share of the data costs incurred (Article 63(3) of the BPR).

Making every effort includes using all reasonable means available to the prospective applicant to contact the data submitter to initiate data-sharing negotiations.

Following their request pursuant to Article 62(2) of the BPR, the Claimant received from the Agency the name and address of the Other Party and the name and email address of one contact person with the Other Party. The Claimant contacted that email address. However, the Other Party sent an automatic out-of-office reply, informing the Claimant that the emails sent to that address would not be read until the person's return. Furthermore, the automatic reply included a name of a substitute person. If an employee is away and names a substitute person to contact, then it can be expected that the sender of a message will contact this person.

However, the Claimant re-sent their data-sharing request to the same email address received from ECHA three times, to no avail, before submitting a data-sharing dispute to ECHA. The Claimant could not know if that person came back and saw the emails, but the Claimant did not use any other means of contacting the Other Party. For example, the Claimant could have contacted the indicated substitute person.

Making every effort also means to make efforts to ensure that your messages will be received and read by the negotiating partner. If it is evident that emails sent to the particular email address are not replied to, contacting the substitute person indicated in the out of office reply is a way to make the negotiations move forward. When the date of return of the contact person is not clear, a party should contact the substitute, if it wants its messages to be replied to and to make every effort to share data. ECHA further notes that in this case, the Claimant had other means of contact available to them, namely the address of the company provided by ECHA in its communication, and the name of the substitute person, provided by the Other Party in the out-of-office reply. Therefore, the Claimant did

⁷ The Claimant; 7 June 2018

⁸ The Claimant; 6 July 2018

not make every effort when they merely sent emails to one email address despite having received information about an alternative contact address. On the other hand, the Other Party made efforts when they informed the Claimant in the out-of-office reply of the absence of the contact person and included the name of the substitute person.

Conclusion

The Claimant did not make every effort to reach an agreement pursuant to Article 63 of the BPR by not exploring any alternative ways available to them to contact the Other Party when they had received information on the contact person's absence with the name of the substitute person, and when they did not receive any reply to their the emails from the Other Party apart from the automatic out-of-office reply.

Annex II: ADVICE AND FURTHER OBSERVATIONS⁹

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. Therefore, ECHA would like to make a general observation in order to facilitate a future agreement.

ECHA encourages data-submitters to keep their contact information with ECHA up-to-date, to enable prospective applicants and the Agency to reach them.

⁹ 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 'Assessment' of Annex I. The Annex II 'Advice and Further Observations' aims only at providing further advice and information that can be helpful for the parties in the future of their discussions on data sharing and joint submission obligations.

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