



covered the exchange of communication up to the date of the claim.

#### The result of the assessment

**As a result of the objective and contradictory assessment, ECHA has decided not to grant you the permission to refer to the information you requested from the existing registrants of [REDACTED] represented by [REDACTED]**

Based on the information provided by both you and [REDACTED] ECHA has concluded that you did not make every effort to reach an agreement on the sharing of information you requested under Article 30(1) of the REACH Regulation.

### **DETAILED OUTCOME OF THE ASSESSMENT OF THE DATA SHARING DISPUTE**

Article 30(1) of the REACH Regulation requires SIEF participants to "make every effort to ensure that the costs of sharing information are determined in a fair, transparent and non-discriminatory way". The following provides the detailed outcome of the objective and contradictory assessment of the data sharing dispute between [REDACTED] (hereinafter referred to as "[REDACTED]") and the existing registrants of [REDACTED] represented by [REDACTED] (hereinafter referred to as "[REDACTED]") under Article 30(3) of the REACH Regulation.

#### Factual background

[REDACTED] initiated<sup>1</sup> the negotiations via email on 28 May 2013 requesting a price quotation for a Letter of Access (hereinafter referred to as "LoA") for the substance [REDACTED] with EC number [REDACTED] at a tonnage band level of [REDACTED] tpa.

[REDACTED] sent<sup>2</sup>, later on the same day, an email explaining the steps required for joining the [REDACTED] registration as follows:

#### Step 1 – Participation in cost sharing/ letter of access (LoA)

The price for registrants with a tonnage band from [REDACTED] tpa is [REDACTED] EUR (plus [REDACTED] EUR as an administration fee), [REDACTED] explains that the "administration fee includes: provision of all necessary documents for registration; provision of the samples to the lab and evaluation of the laboratory data". Finally, they address that "all supplement questions concerning the REACH Regulation or the registration process (per mail or phone) will be invoiced with an hourly rate of [REDACTED] EUR".

#### Step 2 – Test for substance sameness

In order to join the main dossier and to ensure substance sameness, [REDACTED] offers to conduct a test, which costs [REDACTED] EUR.

#### Step 3 – Submission of information

[REDACTED] offers "confirmation of the participation in the joint submission in REACH-IT; creation of the individual dossier for a joint submission based on the IUCLID 5 template; submission of the mandatory-specific registration dossier via REACH-IT and communication with ECHA". This costs [REDACTED] EUR.

#### Step 4 – ECHA

<sup>1</sup> Cf. [REDACTED] email of 28 May 2013.

<sup>2</sup> Cf. [REDACTED] email of 28 May 2013.

█ informs the registrants about ECHA's registration fee depending on the company size and on the turnover of the company.

█ also announces that a webpage for █ registrants is available and lists all the REACH compliant members. This service is free of charge.

█ responded<sup>3</sup> the next day, on 29 May 2013, claiming that for a micro-sized company the proposed LoA costs of █ EUR are "*disproportionately high for that specific substance*" and thus requesting a "*detailed argumentation on the type of the tests performed or to be performed in terms of registration and respective costs of generating data for the main registration dossier of that non-hazardous substance, as well as the criteria for distribution of the costs amongst the SIEF's participants*". Moreover, they asked "*whether some specific analytical tests relevant for the substance in question will be necessary to sufficiently demonstrate the "sameness" with the substance already registered*".

On 31 May 2013, █ confirmed<sup>4</sup> that the LoA costs were still █ EUR plus █ EUR administration fee and asked █ to forward their existing laboratory test results in order to compare them with █ data.

Furthermore, █ offered to pay the LoA costs in three equal instalments, as proposed to micro-sized enterprises.

Finally, █ informed<sup>5</sup> █ on 7 June 2013 of their intention to lodge a data sharing dispute claim before ECHA as the offered LoA price is, in their opinion, "*inexplicably high*".

#### Assessment of the parties' efforts to reach an agreement

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, Article 30(3) of the REACH Regulation requires ECHA to determine whether to grant a permission to refer to the information contained in the registration dossier, i.e. to the corresponding studies. In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the information provided, so as to establish whether the parties have made every effort to ensure that the studies and their costs are shared in fair, transparent and non-discriminatory way.

#### █ efforts

Based on the communication between the parties, ECHA considers that █ has not made every effort to reach an agreement with the existing registrants on the sharing of data under fair, transparent and non-discriminatory conditions.

ECHA expects SIEF participants to negotiate the sharing of data and related costs as constructively as possible to make sure that the negotiations move forward by (i) initiating the negotiations sufficiently early; (ii) replying to the messages of the other party in a timely manner; (iii) taking up their arguments and concerns and (iv) replying and asking

<sup>3</sup> Cf. █ email of 29 May 2013.

<sup>4</sup> Cf. █ email of 31 May 2013.

<sup>5</sup> Cf. █ email of 7 June 2013.

relevant questions. Furthermore, each party shall give reasonable time to the other for providing appropriate answers to its questions.

The claimant first contacted<sup>6</sup> [REDACTED] on 28 May 2013, [REDACTED] and the last exchange of messages between the two parties took place on 7 June 2013 when the claimant informed<sup>7</sup> [REDACTED] of his intention to lodge a data sharing dispute claim before ECHA.

The claim was submitted to ECHA on 10 June 2013. Data sharing negotiations can be a complicated process, where the parties have to identify their respective data requirements and find an agreement on the costs of the data and the modalities of sharing. This typically requires more than 2 weeks. ECHA generally considers that negotiations should be initiated 6 to 12 months [REDACTED] [REDACTED] [REDACTED] [REDACTED] to allow ample time for negotiations.

Finally, the claimant never considered or challenged the alternative payment option proposed by [REDACTED] (i.e. three instalments) in order to unblock the negotiations. This demonstrates that they did not submit their claim as a last resort, and that not all negotiation efforts had been exhausted.

#### [REDACTED] efforts

[REDACTED] requested on 29 May the cost breakdown for the LoA<sup>8</sup>. According to Article 30(1) of the REACH Regulation, "within one month of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it." At the time of submission of the data sharing dispute claim, there was still time for [REDACTED] to provide it within the timeframe required in Article 30(1). In the present case, the claimant submitted the dispute claim to ECHA only twelve days after such request, which is pre-mature.

Based on the documentary evidence submitted, ECHA concluded that [REDACTED] made efforts to advance the negotiations by replying to [REDACTED] emails in a timely manner and by providing without delay information on the cost and conditions of the LoA<sup>9</sup>.

Furthermore, since the claimant had indicated<sup>10</sup> to [REDACTED] that the price is "disproportionately high" for a micro-sized company, [REDACTED] offered<sup>11</sup> the claimant the possibility to pay the LoA costs in three instalments.

Given the little time available for negotiations between the first contact by the claimant and the submission of their claim, i.e. less than 2 weeks, [REDACTED] cannot be held responsible for the fact that the parties did not reach an agreement on the sharing of data.

#### Conclusion

[REDACTED] has therefore not made every effort to reach an agreement on the sharing of costs of the data in a fair, transparent and non-discriminatory way, as required by Article 30(1) of the REACH Regulation.

<sup>6</sup> Cf. [REDACTED] email of 28 May 2013.

<sup>7</sup> Cf. [REDACTED] email of 7 June 2013.

<sup>8</sup> Cf. [REDACTED] email of 29 May 2013.

<sup>9</sup> Cf. [REDACTED] email of 28 May 2013 13:58, in reply to [REDACTED] first email on 28 May 2013.

<sup>10</sup> Cf. [REDACTED] email of 29 May 2013.

<sup>11</sup> Cf. [REDACTED] email of 31 May 2013.

Consequently, ECHA does not grant [REDACTED] with the permission to refer to the requested data in accordance with Article 30(3).

Both parties 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.

#### General observations

Besides the result of the assessment, ECHA would like to make some general observations in order to facilitate a future agreement:

- Making every effort in reaching an agreement requires both potential and existing registrants to find alternative solutions to unblock the negotiations and to be open and proactive in their communications with the other party. In case a party receives an unsatisfactory reply, which it considers unclear, invalid or incomplete, it is the responsibility of the recipient to challenge that answer, by addressing constructive, clear and precise questions or arguments to the sender;
- Each party shall give reasonable time to the other for providing appropriate answers to its questions;
- If the further data sharing negotiations fail, the claimant is free to submit another claim, covering the subsequent efforts. 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 encourages you to continue your efforts to reach an agreement that will be satisfactory for both parties;
- ECHA is never a party in the negotiations. Therefore all arguments have to be communicated between SIEF participants regarding how the costs were defined using for example various percentage premiums;
- Finally, Article 11 of the REACH Regulation imposes on multiple registrants of the same substance to submit one joint submission comprising the shared information.

#### Contact

Should you need to follow up on this particular matter, please contact ECHA using the following email address: [datasharing-disputes@echa.europa.eu](mailto:datasharing-disputes@echa.europa.eu), and stating the above-mentioned EC number and the reference number in any correspondence in relation to this decision.

Yours faithfully,

[REDACTED]  
Geert Dancet  
Executive Director

[REDACTED]  
Jukka MALM  
Director