

25 -02- 2014

[REDACTED]

Sent via REACH-IT to: [REDACTED]

Copy to:

[REDACTED]

Sent via REACH-IT to: [REDACTED]

Reference number: DSH-30-3-[REDACTED]-2013

Decision number: **DSH-30-3-D-[REDACTED]-2013**

DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 30(3) WITH [REDACTED] FOR THE SUBSTANCE WITH EC NUMBER [REDACTED]

Dear [REDACTED],

In accordance with Article 30(3) of Regulation (EC) No 1907/2006 (REACH Regulation), the European Chemicals Agency (ECHA) has examined the claim and information your company, [REDACTED] submitted on 27 November 2013, regarding the failure to reach an agreement on data sharing under Article 30(3) of the REACH Regulation with [REDACTED] representing the existing registrants, for the substance [REDACTED] with EC number [REDACTED].

The information you provided was considered complete and appropriately documented, as indicated in the communication ECHA sent to you on 4 December 2013. ECHA also received the information from [REDACTED] on 10 December 2013 and therefore conducted a contradictory assessment of the information provided by both parties. The assessment covered the exchange of communication up to the date of the claim.

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].

The detailed justification is set out in **Annex** to this decision.

General observations

ECHA would like to make some general observations in order to facilitate a future agreement:

- Making every effort in reaching an agreement requires both the 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 the parties to continue their 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.

Finally, Article 11 of the REACH Regulation imposes on multiple registrants of the same substance to submit one joint submission comprising the shared information.

Appeal

In accordance with Article 30(5) of the REACH Regulation, both parties involved in the dispute may appeal against this decision to the Board of Appeal of ECHA within three months of the notification of this decision. The procedure for lodging an appeal is described at <http://echa.europa.eu/web/guest/regulations/appeals>.

Contact

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

Yours faithfully,



Christel Schilliger-Musset
Director of Registration

Annex:

Detailed outcome of the assessment of the data sharing dispute

Annex to decision DSH-30-3-D-██████-2013**DETAILED OUTCOME OF THE ASSESSMENT OF THE DATA SHARING DISPUTE**

The following provides the detailed outcome of the objective and contradictory assessment of the data sharing dispute between ████████ (hereinafter referred to as "██████") and the existing registrants of ████████ represented by ████████ (hereinafter referred to as "██████"), under Article 30(3) of the REACH Regulation.

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

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 reach an agreement on the sharing of studies and their costs in a fair, transparent and non-discriminatory way.

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. In order to make every effort to reach an agreement, SIEF participants shall negotiate the sharing of data and related costs as constructively as possible to make sure that the negotiations move forward by taking up their arguments and concerns, as well as replying and asking relevant questions.

██████ initiated¹ the negotiations on 26 February 2013 asking for an offer on the sharing of data in order to proceed with the registration. On 11 March 2013, ████████ replied², explaining the steps required for joining the ████████ registration, including the purchase of the Letter of Access (hereinafter referred to as "LoA") as well as the corresponding cost.

After this first email exchange, the claimant indicated in his second email of 5 September 2013 that they have pre-registered the substance ████████ for the tonnage band ████████ t/y and they have the "*technical capability to increase the plant capacity to ████████ t/y*". In the same email, they informed that their "*company is a micro enterprise*". Finally, ████████ did not question the cost indicated by ████████ but requested "*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*"³. This request for sufficiently detailed information on the cost calculation was an important initial contribution to advancing the negotiations in a constructive manner. Without this essential information, the negotiations cannot move forward, and the potential registrant is not in the position to decide whether the LoA pricing was calculated in a fair, transparent and non-discriminatory way. ECHA notes that, by requesting this information, ████████ demonstrated its intention to contribute proactively to the negotiations.

¹ Cf. ████████ email of 26 February 2013.

² Cf. ████████ email of 11 March 2013.

³ Cf. email of 8 September 2013.

Although [REDACTED] received an out of office message from the first contact person they repeated their attempts to move forward the negotiations with sending their email also to two other contact persons indicated in the out of office message. When they did not receive a reply, they sent the same email to the main contact email of [REDACTED] as well.⁴

[REDACTED] replied on 7 October 2013 and later on 17 October 2013 and they offered the possibility for micro and small companies of paying the price of the LoA ([REDACTED] €) in instalments.⁵ ECHA notes that, by offering this possibility, [REDACTED] demonstrated specific efforts to facilitate an agreement with micro and small companies.

On 6 November 2013, [REDACTED] returned by asking whether the “*increasing number of registrants (joint submission – so far 70 companies)*”⁶ has affected the price for the LoA.

One week later, on 13 November 2013, [REDACTED] repeated the offer of the three instalments for the micro- or small-sized companies. In addition, [REDACTED] enclosed the breakdown of the costs of the studies. By providing the cost breakdown, [REDACTED] addressed the [REDACTED] request, which was an essential contribution to the negotiations. Regarding the price of the LoA, [REDACTED] also addressed [REDACTED] request that it will “*be discussed within the CPO [Contractual Partner Organisation] in the very next time. If all potential registrants would register now, the costs per registrant will decrease significantly*”.⁷ [REDACTED] also repeated his “*promise to recalculate the price in reasonable intervals*” in the email of 20 November 2013.

In spite of all the information provided by [REDACTED] in its email of 13 November 2013, ECHA notes that [REDACTED] never challenged the position of [REDACTED] and more particularly the breakdown of the costs of the studies. Rather, [REDACTED] merely claimed that the price of the LoA is “*very high*”⁸, without substantiating its claim with any argument challenging the cost breakdown. In the absence of argument justifying any disproportion of the cost required, [REDACTED] did not contribute effectively to the data sharing negotiations.

If [REDACTED] had any reason to disagree with the conditions for sharing the data, they should have provided the other party with relevant arguments, placing them in a position to justify or clarify their claim and allowing the negotiations to continue until an agreement is finally reached. Instead, [REDACTED] submitted a data sharing dispute to ECHA.

Based on the above, ECHA concludes that [REDACTED] has not made every effort to reach an agreement with the existing registrants 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.

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

ECHA stresses that, irrespective of the present decision, both parties are still subject to the data sharing obligation and they are therefore still required to make every effort to reach an agreement on the sharing of the information and of their related cost.

⁴ Cf. [REDACTED] emails of 5 September, 8 September, 25 September and 4 October 2013

⁵ Cf. [REDACTED] email of 17 October 2013.

⁶ Cf. [REDACTED] email of 6 November 2013

⁷ Cf. [REDACTED] email of 13 November 2013

⁸ Cf. [REDACTED] email of 17 October, 19 November and 20 November 2013.