

25. 10. 2013

[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 Mr [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 9 August 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 16 August 2013. ECHA also received the information from [REDACTED] on 30 August 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 I** 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 above-mentioned EC number and the reference number in any correspondence in relation to this decision.

Yours faithfully,



Geert Dancet
Executive Director

Annexes:

Annex I: Detailed outcome of the assessment of the data sharing dispute

Annex I to decision DSH-30-3-D[REDACTED]-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 [REDACTED] (hereinafter referred to as [REDACTED] and the existing registrants of [REDACTED] represented by [REDACTED] [REDACTED] (hereinafter referred to as [REDACTED] under Article 30(3) of the REACH Regulation.

Based on the information provided by both [REDACTED] and [REDACTED] ECHA has concluded that [REDACTED] did not make every effort to reach an agreement on the sharing of information you 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.

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 (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 relevant questions.

[REDACTED] initiated¹ the negotiations on 25 February 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. Later on the same day, [REDACTED] replied², explaining the steps required for joining the [REDACTED] registration, which includes the purchase of the LoA, the agreement on the substance sameness, and the payment of the registration fee to ECHA. [REDACTED] also offered some optional services.

After this first email exchange, the claimant indicated in his second email of 28 February that the price is "*too high*" and requested "*further information regarding the exact price calculation*". This request was an important initial contribution to advancing the negotiations in a constructive manner.

[REDACTED] replied on the same day that "*there is no possibility to lower the price. The price is so high because of the missing registrants*". They also claimed that as "*the more registrants really fulfil their requirements and share the costs*", they "*can start the reimbursement*". Besides, [REDACTED] announced that "*the LoA is re-calculated once a year*" and that it has been scheduled "*next time in June [2013] [REDACTED]*".³

Although [REDACTED] did not provide the requested information regarding the exact price calculation, ECHA notes that [REDACTED] never communicated again with the existing registrants.

¹ Cf. [REDACTED] email of 25 February 2013.

² Cf. [REDACTED] email of 25 February 2013.

³ Cf. [REDACTED] email of 28 February 2013.

On 9 August 2013, [REDACTED] submitted the data sharing dispute claim to ECHA under Article 30(3), requesting the permission to refer to the data submitted by the previous registrants of [REDACTED].

However, ECHA expects that 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 clear and precise questions or arguments to the other party, especially in such a case, where ample time remained [REDACTED].

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. ECHA considers one attempt is generally not sufficient to demonstrate that every effort has been made to reach an agreement.

The fact that [REDACTED] never responded to [REDACTED] email of 28 February 2013, [REDACTED] [REDACTED] [REDACTED] could have been understood by [REDACTED] either, as the sign that [REDACTED] no longer had the intention to register or that [REDACTED] agreed with [REDACTED] proposal. If [REDACTED] still had the intention to submit a registration dossier while disagreeing with the condition for sharing the data, they should have continued the negotiations with the existing registrants before submitting a data sharing dispute to ECHA.

Although [REDACTED] initiated the negotiations between the parties, the above demonstrates that not all efforts had been exhausted before submitting their data sharing claim to ECHA.

Based on the communication between the parties, ECHA concludes that [REDACTED] [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).

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.