ECHA
EUROPEAN CHEMICALS AGENCY

CONFIDENTIAL

16. 08. 2013

[redacted]

Sent via REACH-IT to: [redacted]

Copy 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 30 May 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].

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, 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 related costs are shared in fair, transparent and non-discriminatory way.

Documentary evidence

The information you provided was considered complete and appropriately documented, as indicated in the communication ECHA sent to you on 31 May 2013. ECHA did not receive information from [redacted] within the deadline set to 18 June 2013 and therefore conducted an assessment solely based on the information submitted by you. The assessment covered the exchange of communication up to the date of the submission of the claim.

The result of the assessment

As a result of the objective 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 you and available to ECHA, 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 assessment of the data sharing dispute between [redacted] (hereinafter referred to as "[redacted]" or "the claimant") 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 the negotiations via email on 15 May 2013[1], expressing their wish to register their pre-registered substance [redacted] as part of a joint submission by [redacted]. They also requested a quote for a Letter of Access (hereinafter referred to as "LoA") to the joint submission dossier.

[redacted] responded[2] to this message on the following day providing information on the conditions of use and purchase of the LoA as well as quoting the costs of the LoA at €[redacted]. Furthermore they attached a LoA order form, information on their substance identity and a SIEF agreement. In order to accelerate the LoA purchase process and thus to enable [redacted] to submit their registration dossier in time, [redacted] asked [redacted] to provide them with "*the scanned version [of the signed documents] anticipated per email*".

[redacted] replied[3] to this message on the same day claiming that the offer was "*tremendously high*" and stating that "*the max amount [redacted] are ready to pay for such registration as a part of the individual registration is Eur [redacted]*".

On 17 May 2013 [redacted] responded[4] that "*the cost of a letter of access is not a question of commercial negotiation*" as the costs are divided among the members of the joint submission. Moreover, [redacted] confirmed the cost of €[redacted] once more. In the same message they also informed that they would "*run a check of the account after [redacted] to decide on eventual refunds or additional charges*".

The claimant replied[5] on the same day that the requested amount is "*out of question since [redacted] have offers for co-registration of other products on the range of [redacted] usd*" and continues "*We are not dispose to pay more than that amount*".

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[1] Cf. [redacted]' email of 15 May 2013.
[2] Cf. [redacted]'s email of 16 May 2013, 15:32.
[3] Cf. [redacted]' email of 16 May 2013.
[4] Cf. [redacted]'s email of 17 May 2013, 12:46.
[5] Cf. [redacted]' email of 17 May 2013.

Still on 17 May 2013, [redacted] explained[6] that they cannot change their position because as leader of a joint submission they "*have to care that all co-registrants are treated in the same way*". They also repeated their intention to refund or to charge additional costs to each co-registrant depending on the final number of registrants related to [redacted], as the costs were based on a survey on intentions to register.

[redacted] responded[7] to this email by claiming that the quoted amount was not justified and requested to "*consider once again and offer better and reasonable conditions*".

[redacted] reacted[8] to this message on 20 May 2013 maintaining their position that "*this is not a commercial question with negotiation of more or less best offers*" and repeating that once the final number of co-registrants is established, the costs will be recalculated.

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.

[redacted]' efforts

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

To make every effort to reach an agreement, a potential registrant must do everything that can reasonably be expected of him to reach an agreement. As a very minimum, this includes initiating the negotiations sufficiently early to make it possible to reach an agreement. ECHA generally considers that negotiations should be initiated 6 to 12 months [redacted]. It is also indispensable that the registrants understand that they are sharing data, which they need in their registration dossier under REACH to demonstrate the intrinsic properties of the substance they are manufacturing or importing. Not only the data, but also their costs are to be shared in a fair, transparent and non-discriminatory manner. To advance negotiations on data sharing, sufficiently detailed information on the cost calculation is crucial. Therefore, to constructively challenge a proposed price, a potential registrant must ask the existing registrants which data are covered by the joint submission and what are the costs of this data. Upon receipt of the reply, the potential registrant may attempt to find a common understanding with the existing registrants on the data that is necessary and on its related costs.

The claimant first made contact with [redacted] on 15 May 2013, [redacted]

[6] Cf. [redacted]'s email of 17 May 2013, 17:59.
[7] Cf. [redacted]' email of 17 May 2013 (referred to by the claimant as "Message Nr 8", no exact date/ time is provided in the documentary evidence submitted).
[8] Cf. [redacted]'s email of 20 May 2013, 16:26.

[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. As indicated above, this typically requires more than 3 weeks. To make every effort to reach an agreement, [redacted] should have allowed more time for the negotiations on data sharing and taken contact with the existing registrants earlier.

The communication between [redacted] and [redacted] furthermore shows that [redacted] did not make an effort to understand the subject of the negotiations on data sharing. [redacted] never asked for a breakdown of the costs of the studies covered by the LoA, their respective value or the number of expected registrants. Instead of questioning the price proposed by [redacted] or asking for such a breakdown of costs, [redacted] declared a maximum price, which they would be willing to pay, and which was not set in relation to the costs of the data included of the joint registration dossier[9]. The final price of the shared data cannot be the outcome of the haggling between the parties. The costs of the data to be shared must be the same for all registrants with the same data requirements and must reflect the value of that data.

[redacted]'s efforts

[redacted] made efforts to advance the negotiations by replying to [redacted]' emails in a timely manner and providing information on the cost and conditions of the LoA without delay[10]. Furthermore, [redacted] has established a reimbursement scheme to ensure equal sharing of the costs among the co-registrants and explained this to the claimant on several occasions[11]. Also, [redacted] showed its intention[12] to accelerate the LoA purchase process and thus to enable [redacted] to submit their registration dossier in time by offering [redacted] to start processing their order upon receipt of the scanned version of the signed documents.

[redacted] could have provided a detailed cost breakdown on their own initiative to explain their costs sharing calculations. This would indeed have been a good practice, but may not always be necessary for the negotiations. However, when requested, an existing registrant is obliged to provide the cost breakdown within one month pursuant to Article 30(1)(2) of the REACH Regulation.

Given the short time available for negotiations and the lack of constructive contributions from the claimant's side, [redacted] cannot be held responsible for the fact that the parties did not reach an agreement on the sharing of data.

Conclusion

[redacted] has 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.

ECHA can only grant a permission to refer, where the claimant has made every effort to ensure that the costs of sharing data are determined in a fair, transparent and non-discriminatory way. As [redacted] did not make every effort in this regard, ECHA does not provide the permission to refer to the requested data in accordance with Article 30(3).

[9] Cf. [redacted]' e-mail of 16 May 2013.
[10] Cf. [redacted]'s email of 16 May 2013, 15:32.
[11] Cf. [redacted]'s emails of 17 May 2013 12:46 and 17:59 and of 20 May 2013, 16:26.
[12] Cf. [redacted]'s email of 16 May 2013, 15:32.

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 and 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 where 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.

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,

[redacted]
Jukka MALM
Director

Geert Dancet
Executive Director