

[REDACTED]

Sent via REACH-IT to: [REDACTED]

Copy to:

[REDACTED]

Sent via REACH-IT to: [REDACTED]

Reference number: DSH-30-3-[REDACTED] 2014

Decision number: **DSH-30-3-D**[REDACTED] 2014

**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 9 January 2014, 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] represented by [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 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 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 a fair, transparent and non discriminatory way.

The information you provided was considered complete and appropriately documented, as indicated in the communication ECHA sent to you on 31 January 2014. ECHA also received documentation on the negotiations from [REDACTED] on 31 January 2014 and therefore conducted an objective and contradictory assessment of the information provided by both parties. The assessment 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]**

The detailed justification is set out in the **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 the 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](mailto:datasharing-disputes@echa.europa.eu), and stating the above-mentioned reference number in any correspondence in relation to this decision.

Yours faithfully,



Christel Musset  
Director of Registration

Annex:

Detailed outcome of the assessment of the data sharing dispute

**Annex to decision DSH-30-3-D-██████████2014****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.

This objective and contradictory assessment takes into account the entire process based on the information provided by ██████████ and ██████████ and consequently includes and re-assesses information which were part of the previous data sharing dispute claim with reference number DSH-30-3-██████████-2013.

**Based on this information, ECHA has decided *not* to grant you the permission to refer to the information you requested from the existing registrants of ██████████ represented by ██████████**

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 expressing their arguments and concerns, and replying and asking relevant questions.

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

██████████ sent<sup>2</sup>, later on the same day, an email explaining the steps required for joining the ██████████ registration, including the purchase of LoA.

██████████ responded<sup>3</sup> the next day, 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*". This request for sufficiently detailed

<sup>1</sup> Cf. ██████████ email of 28 May 2013.

<sup>2</sup> Cf. ██████████ email of 28 May 2013.

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



Information on the cost calculation was an important initial contribution to advancing the negotiations in a constructive manner.

On 13 November 2013, [REDACTED] supplied a number of updated documents including *inter alia* the cost breakdown for the registration dossier as well as per endpoint study. By providing the cost breakdown, [REDACTED] addressed [REDACTED]'s request, which was an essential contribution to the negotiations. 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, therefore providing the cost breakdown shows an increase of efforts in transparency by [REDACTED].

In addition, [REDACTED] offered the possibility for SMEs to pay in instalments<sup>4</sup>, highlighting that with receipt of the first instalment registrants will receive all data required for their registration. ECHA notes that, by offering this possibility, [REDACTED] demonstrated specific efforts to facilitate an agreement with micro companies.

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 "high", without substantiating its claim with any argument challenging the cost breakdown. In the absence of arguments justifying any disproportion of the cost required, [REDACTED] did not contribute effectively to the data sharing negotiations.

At the same time, following [REDACTED] repeated requests about lowering the price of the LoA, on 13 December, [REDACTED] provided<sup>5</sup> an updated calculation for the LoA based on the current number of registrants listed in REACH-IT, including the individual registrants. The new price was quoted at [REDACTED] EUR ([REDACTED] t/y). The recalculation of the LoA prices shows further efforts by [REDACTED] towards reaching an agreement on sharing data and related costs. [REDACTED] repeated the offer to pay in instalments, and sent the current cost breakdown for the registration dossier. Further, as there are more potential registrants joining the registration for [REDACTED], [REDACTED] committed to informing [REDACTED] "*when it is foreseeable that a new calculation of the LoA will have an effect on your invoice or instalments*".

After receipt of the updated LoA prices on 13 December 2013, [REDACTED] did not continue the negotiations. If [REDACTED] still 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 communication between the parties, 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 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.

<sup>4</sup> Cf. [REDACTED] email of 31 May, 10 September and 13 November 2013.

<sup>5</sup> Cf. [REDACTED] email of 29 May, 25 September and 9 December 2013.

<sup>6</sup> Cf. [REDACTED] email of 13 December 2013.