

25. 10. 2013

[REDACTED]

Sent via REACH-IT to: [REDACTED]

Copy to: [REDACTED]

[REDACTED]

[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 12 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]

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 reach an agreement on sharing of studies and their related costs 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 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.

The result of the assessment

**As a result of the objective and contradictory assessment, ECHA grants you the**

**permission to refer to the information involving testing on vertebrate animals you requested from the existing registrants of [REDACTED], represented by [REDACTED]**

Based on the information provided by you and [REDACTED], ECHA has concluded that you have made every effort, whereas the existing registrants, represented by [REDACTED] did not make every effort to reach a fair, transparent and non-discriminatory agreement on the sharing of information you requested under Article 30(1) of the REACH Regulation.

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

Scope of the permission to refer

This permission to refer concerns the studies involving testing on vertebrate animals, which were subject to the negotiations on data sharing, i.e. those that are part of the joint submission as contained in the registration dossier submitted by the lead registrant [REDACTED]

Accordingly, the permission to refer concerns the studies submitted for the following endpoints:

1. [REDACTED]
2. [REDACTED]
3. [REDACTED]
4. [REDACTED]

These are contained in **Annex II** to this decision.

Legal consequences and obligations

According to the REACH Regulation, your company may only use this information "*for the purposes of registration*" (as per Articles 10 and 30(3) of the REACH Regulation) and must respect any property rights covering the information. As you have no property rights over these data, you cannot make it available to third parties.

Note that it is your responsibility when registering to fulfil the legal requirements relating to the content of your dossier and to assess the attached data. Please note that ECHA has not assessed its quality or compliance with the REACH requirements (e.g. Klimisch score, GLP status, guidance reference) for the purposes of this claim.

Please follow the instructions in **Annex III** on how to use the information provided by ECHA as a result of this decision to submit your registration dossier. In addition, it is your responsibility to fulfil the legal requirements relating to the chemical safety report and recommended risk reduction measures under Article 14(3) of the REACH Regulation.

According to the Article 30(3) of the REACH Regulation, the existing registrants, represented by the [REDACTED] shall have a claim on you for an equal share of the costs, which shall be enforceable in the national courts, provided that the full study report(s) is made available to you.

Please be reminded that Article 30(3) of the REACH Regulation only refers to requests among SIEF participants regarding vertebrate animal data. If you need to complete your dossier with studies not involving vertebrate animals and you have not been successful in reaching an agreement on the sharing of those data, Article 30(4) applies. It provides that

the potential registrant "*shall proceed with registration as if no relevant study was available in the SIEF*". This entails that, in order to fulfil your registration requirements relating to your registration tonnage band, you find another source to access data or you perform these studies either on your own, or together with other potential registrants facing similar difficulties. Nevertheless, Article 30(6) of the REACH Regulation empowers the Member States to penalise the owner of any study who has refused to provide it upon request.

According to Article 11(1), both you and the other registrants of the same substance need to comply with the joint submission obligations. If this would prove impossible<sup>1</sup>, you would need to prepare and submit a separate registration. As a consequence, you will not be entitled to benefit from the reduced registration fee for joint submissions as defined in Regulation (EC) No 340/2008 on the fees and charges payable pursuant to the REACH Regulation.

### 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>.


### General observations

ECHA would like to point out that the outcome of a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would. Accordingly, should you wish to avoid any inconveniences resulting from this decision, ECHA encourages you to continue your efforts to reach an agreement that will be satisfactory for both parties.

### 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,



Geert Dancet  
Executive Director

### Annexes:

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

Annex II: Endpoint study records assessed in vertebrate animals and related to the properties of the substance with EC number 

Annex III: Instructions on how to submit your registration dossier after resolution of the data sharing dispute procedure

<sup>1</sup> In such case, the complaints may be brought to the National Authority competent for REACH.

**Annex I to decision DSH-30-3-D[REDACTED]-2013****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]" 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

The negotiations started on 22 January 2013 when [REDACTED] contacted [REDACTED] via e-mail and requested "to receive more detailed information about the registration of [REDACTED]".

On 23 January 2013 [REDACTED] sent a standard email explaining the steps required for joining the [REDACTED] registration, which includes the purchase of the Letter of Access (LoA), the agreement on the substance sameness, and the payment of the registration fee to ECHA. [REDACTED] also offered some optional services.

On 22 February 2013, [REDACTED] confirmed to [REDACTED] that their tonnage falls within the [REDACTED] t/y tonnage band. The claimant also informed that "they have completed a sameness substance" form and requested "further information on the expected costs to be shared" together with the number of the registrants. [REDACTED] continued by asking whether they need "additional tests/ certificates" apart from the aforementioned substance test, and where they can find the individual forms required or the link to retrieve them and sending back after filling.

On 25 February 2013, [REDACTED] sent an email to [REDACTED] asking for "an offer for the LoA for the tonnage band of [REDACTED] t/y".

On the same day, [REDACTED] merely replied to [REDACTED] earlier emails that the registration fee "is for ECHA and depends on your company size". [REDACTED] also claimed that they have not yet sent the LoA agreement because "there are different for the different tonnage bands". Finally, [REDACTED] claimed that as soon as they prove the substance sameness and that the LoA is paid by the claimant, they will "provide the necessary document they need to complete the registration".

On 26 March 2013, [REDACTED] requested "an update on the current status of process" and asked whether there are any changes on the "LoA costs" announced on 23 January 2013. The claimant also explained that the "price [REDACTED] have established is completely outside of the financial capabilities of small firms like [REDACTED]". Finally, [REDACTED] proposed "a segmentation process for the cost sharing program" according to which "businesses are separated into different categories not only based on the tonnage band, but also based on their revenue and employee count".

On 16 May 2013 [REDACTED] sent a reminder to [REDACTED] related to the email of 26 March 2013. [REDACTED] did not reply either to the proposal or to this reminder.

On 12 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 existing registrants of [REDACTED]

#### 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 conducted an assessment of all the information provided to establish whether the parties have made every effort to reach an agreement on the sharing of studies and their costs in 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. Furthermore, each party shall give reasonable time to the other for providing appropriate answers to its questions.

[REDACTED] started the negotiations sufficiently early. They made contact with [REDACTED] by e-mail in January 2013<sup>1</sup>. It is fair to assume that the parties could have found an agreement within this four-month period [REDACTED], had they not encountered disagreement on the LoA pricing.

On 22 February, the claimant requested *"further information on the expected costs to be shared"* together with the number of the registrants<sup>2</sup> for the registration of the lead dossier. This was an important 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. [REDACTED] response of 25 February<sup>3</sup> was not answering the questions. The claimant never received a response to his request<sup>4</sup>. Should they have received a reply, the parties could have further discussed the necessary data and the appropriate method of calculating the costs. Thus, the negotiations could possibly have been successful. As it were, however, the negotiations were blocked.

On 26 March, the claimant requested *"an update on the current status of process"*. This follow-up question was also essential to make sure the negotiations move forward. However, [REDACTED] never replied to this request for update either.

In the same email, the claimant made further efforts to move the negotiations on by proposing an alternative solution on the sharing of the costs and by explaining why they considered the price as high. Making every effort in reaching an agreement requires the parties to find alternative solutions to unblock the negotiations and to be open and proactive in their communication. This alternative proposal could have contributed to finding a common understanding on the proportionality of the price. However, it was never addressed or challenged by [REDACTED]

<sup>1</sup> Cf. [REDACTED] e-mail of 22 January 2013

<sup>2</sup> Cf. [REDACTED] e-mail of 22 February 2013.

<sup>3</sup> Cf. [REDACTED] email of 25 February 2013.

<sup>4</sup> Cf. [REDACTED] e-mail of 26 March 2013.

Finally, on 16 May [REDACTED] sent a final reminder<sup>5</sup> to the other party in order to unblock the negotiations and to show willingness to keep the efforts to reach an agreement. Sending this reminder was also crucial for progress the negotiations, especially so close to the registration deadline. [REDACTED] did not reply either to the original proposal or to the reminder.

### Conclusion

ECHA concludes that [REDACTED] has made every possible effort, however, the existing registrants, represented by [REDACTED] have not made every effort to reach an agreement on the sharing of data and their costs in a fair, transparent and non-discriminatory way, as required by Article 30(1) of the REACH Regulation. Consequently, ECHA provides [REDACTED] [REDACTED] with the permission to refer to the requested data in accordance with Article 30(3).

The existing registrants shall have a claim on [REDACTED] for an equal share of the costs, providing that they make the corresponding full study reports available, which shall be enforceable in the national courts.

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<sup>5</sup> Cf. [REDACTED] email of 16 May 2013.