EUROPEAN CHEMICALS AGENCY

CONFIDENTIAL

16. 08. 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 5 June 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 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 12 June 2013. ECHA also received the information from [redacted] on 26 June 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[1], 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, 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

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 [redacted]

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

[1] 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 19 February 2013 when [redacted] contacted [redacted] via e-mail and announced their intention to participate in the joint submission by asking an offer to join the joint submission.

Following this e-mail, [redacted], later on the same day, sent an email explaining the steps required for joining the [redacted] registration as follows:

Step 1 – Participation in cost sharing/ letter of access (LoA)

The price for registrants with a tonnage band from [redacted] tpa is [redacted] EUR (plus [redacted] EUR as an administration fee), [redacted] explains that the "*administration fee includes: provision of all necessary documents for registration; provision of the samples to the lab and evaluation of the laboratory data*". Finally, they address that "*all supplement questions concerning the REACH Regulation or the registration process (per mail or phone) will be invoiced with an hourly rate of [redacted] EUR*".

Step 2 – Test for substance sameness

In order to join the main dossier and to ensure substance sameness, [redacted] offers to conduct a test, which costs [redacted] EUR.

Step 3 – Submission of information

[redacted] offers "*confirmation of the participation in the joint submission in REACH-IT; creation of the individual dossier for a joint submission based on the IUCLID 5 template; submission of the mandatory-specific registration dossier via REACH-IT and communication with ECHA*". This costs [redacted] EUR.

Step 4 – ECHA

[redacted] informs the registrants about ECHA's registration fee depending on the company size and on the turnover of the company.

[redacted] also announces that a webpage for [redacted] registrants is available and lists all the REACH compliant members. This service is free of charge.

[redacted] provided ECHA with an attachment, which seems to have been sent on 4 March 2013, by the chairman of the [redacted] (representing 21 micro enterprises). This communication has not been taken into account to the assessment conducted by ECHA since it contains no reference to [redacted] and there is no sufficient evidence (recipient address, time and full date) that it was sent to [redacted].

On 5 April 2013, [redacted] sent an e-mail to [redacted] in which they claimed that *"still have not received any meaningful justification for the high pricing of the dossier for chemical safety"* and that they are convinced that the price [redacted] is demanding for the LoA is *"disproportionately high"* because [redacted] *"refuse to show on what ground it is formed"*.

[redacted] also adds that they *"have estimated the costs for the dossier at [redacted] EUR"* and can offer *"the breakdown of the costs for the Letter of Access at that price."*

Besides, [redacted] warns [redacted] that they will inform ECHA and will *"initiate individual registration procedure for '[redacted]' producers in the range of [redacted] tons annually"*. Further, [redacted] informs [redacted] that they have discussed the issue with local colleagues and that *"none of them have received any explanation on the formula used to calculate the costs."*

On 29 May 2013, [redacted] sent an e-mail to [redacted] asking for any *"change in the price of the LoA"* and explained why they cannot afford *"the announced costs for data sharing for joint submission"*. Besides, [redacted] requested 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, as well as the criteria for distribution of the costs amongst the SIEF's participants."*

[redacted] responded on the same day to [redacted] that *"it's not [their] money [they] are talking about"* but that they are *"responsible for the administration and equal cost sharing."* In the same e-mail, [redacted] claimed that as the number of the registrants will increase, the price of the LoA will decrease. Besides, [redacted] offered the possibility to the claimant of paying the price for the LoA in three instalments, the first third when receiving the token for the joint submission, the next third half a year later and finally the last one year after the first instalment.

[redacted] replied on 5 June 2013 that due to the *"unjustified price"* and the refusal of [redacted] to provide *"with information on the costs incurred to register the substance [redacted]"* decided to *"inform the European Chemicals Agency"* about *"the difficulties encountered in implementing the requirements of [the REACH] Regulation."*

On 5 June 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].

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 ensure that the studies and their costs are shared in fair, transparent and non-discriminatory way.

Admissibility

The data sharing dispute is admissible. Especially, its subject matter was clearly identified.

The studies relating to a data sharing dispute were clearly identified. The parties negotiated the LoA for the joint submission registration of [redacted] at the tonnage band of [redacted] tonnes per year. The studies involving vertebrate animal testing that were the subject of the negotiations and, by extension, of the data sharing dispute before ECHA, are thus all vertebrate animal studies required for Annexes [redacted] of the REACH Regulation and available in the lead dossier for [redacted]. Annex II to this decision lists the specific studies covered by the decision.

[redacted]'s efforts

[redacted] started the negotiations sufficiently early. They made contact with [redacted] by e-mail in February 2013[1]. It is fair to assume that the parties could have found an agreement within these three and a half months [redacted], had they not encountered disagreement on the LoA pricing.

The submission of the dispute was also not premature, as the last emails[2] show that the negotiations had reached a standstill, because the parties had exchanged their arguments on the LoA pricing and there was no more time for negotiations [redacted].

By asking the representative of the existing registrants for a breakdown of the LoA costs[3] incurred for the registration of the lead dossier, [redacted] addressed the original proposal of [redacted] and demonstrated their constructive efforts in the negotiations. To advance negotiations on data sharing, sufficiently detailed information on the cost calculation is crucial. [redacted] never received a response to this request. 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.

Nevertheless, the claimant made further efforts to unblock the negotiations by indicating that he is willing to provide his own calculation of the costs as an alternative solution[4], which was never addressed or challenged by [redacted]. Also, these questions could have contributed to finding a common understanding on the proportionality of the price.

Finally, [redacted] informed ECHA about the disagreement by submitting a data sharing dispute claim [redacted], when all the efforts to find an agreement had been exhausted.

[redacted]'s efforts

Although [redacted], on behalf of the existing registrants, made some efforts to reach an agreement with [redacted] by providing an alternative solution to pay the LoA, i.e. to pay it in three instalments, and to potentially reduce the price of the LoA, when the number of the registrants increase[5], ECHA concludes that they did not make *every effort* to reach a *fair, transparent and non-discriminatory* agreement.

[redacted] were not very responsive as they did not reply swiftly to all messages of [redacted]. There is even a period of almost two months[6] without any response. It thereby showed a lack of

[1] Cf. [redacted]'s e-mail of 19 February 2013.
[2] Cf. [redacted]'s and [redacted]'s e-mails of 29 May 2013 and [redacted]'s e-mail of 5 June 2013.
[3] Cf. [redacted]'s e-mails of 5 April 2013, 29 May 2013 and 5 June 2013.
[4] Cf. [redacted]'s e-mail of 5 April 2013.
[5] Cf. email from [redacted] of 29 May 2013.
[6] Cf. email from [redacted] of 5 April 2013 and reminder of 29 May 2013.

efforts, as REACH requires the existing registrants to act in a pro-active, informative, transparent and responsive manner towards potential registrants, particularly if the potential registrants have not been part in the process of selecting the data submitted and deciding on the sharing of the cost, or if their legal knowledge of REACH may be less extensive. Providing the overview of the registration process of [redacted] did not amount to making every effort to reach an agreement. The potential registrant was not asked to contribute to any discussion related to data sharing and related costs, but was merely informed on the outcome of the discussion among the existing registrants[7], as a fait accompli.

Furthermore [redacted] repeatedly requested[8] the breakdown of costs incurred for the LoA in order to gain knowledge of what they are about to pay for. [redacted] did not reply to their request, even after one month, despite their obligation according to Article 30(1) of the REACH Regulation, which clearly states that "*within one month of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it.*" Providing this information when requested is a necessary part of negotiating the sharing of data and related costs. Without a common understanding of the calculation of the price, the parties are not in a position to find an agreement on the sharing of the data and their related costs.

Where the existing registrants refuse to provide the breakdown of the costs, they breach their obligation as well as show a lack of effort and make it impossible to reach a *fair, transparent and non-discriminatory agreement.*

[redacted] claimed to ECHA that [redacted] never asked targeted questions related to substance properties, specific endpoints or access to vertebrate animal studies. As explained earlier, ECHA notes that the parties negotiated the LoA for the joint submission registration of [redacted] at the tonnage band level of [redacted] tonnes per year. Thus all data required for Annexes [redacted] of the REACH Regulation and available in the lead dossier for [redacted] were subject to the negotiations. A breakdown of the costs for a LoA should have included all the studies concerned and their value, as well as the related administrative or other costs. [redacted] did not provide any of these, therefore their claim is not appropriate.

Conclusion

The existing registrants, represented by [redacted], have therefore 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] 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.

[7] Cf. email from [redacted] of 29 May 2013.
[8] Cf., emails from [redacted] of 5 April and 29 May 2013