ECHA
EUROPEAN CHEMICALS AGENCY

CONFIDENTIAL

[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 THE EXISTING REGISTRANTS OF [redacted] (WITH LIST 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 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 of [redacted] with list 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 13 May 2013. ECHA also received the information from [redacted] on 28 May 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 both you and the other party, ECHA has concluded that you have made every effort, whereas the existing registrants, represented by the [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 existing registrants of [redacted] with list number [redacted], and which [redacted] is entitled to share with other registrants.

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

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [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.

[redacted]

Please follow the instructions in **Annex III** on how to use the information provided by ECHA as a result of this decision to update 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 [redacted] shall have a claim on you, for an equal share of the cost, 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.

[1] In such case, the complaints may be brought to the National Authority competent for REACH.

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 reference number in any correspondence in relation to this decision.

Yours faithfully,

[redacted]

Geert Dancet
Executive Director

Annexes:

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

Annex II: Endpoint study records involving vertebrate animal testing, for which permission to refer has been granted for the substance with list number [redacted]

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

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] and [redacted] under Article 30(3) of the REACH Regulation.

Factual background

The negotiations started on 28 January 2013, when the claimant, [redacted], first approached [redacted] (a representative of [redacted]) to express an interest in sharing data[1] for [redacted] products and to request information on how to "join the group or share information already provided to REACH"[2].

[redacted] (hereinafter called "consortium") representing the existing registrants of the substance [redacted] replied on the same day by offering either the membership in the consortium or the purchase of a Letter of Access (LoA) as possible options to share data. Furthermore, [redacted] was asked to sign and return a non-disclosure agreement[3], which was submitted on the following day[4].

Further to a reminder by the claimant[5], the consortium sent a SIEF and consortium agreement to [redacted] on 4 February 2013. In the SIEF agreement non-consortium members were required to provide a bank guarantee of € [redacted][6]. The claimant reverted to the consortium[7] indicating "I am really struggling to see how I can afford to pay such high membership joining charges" and thus requesting "Please can you offer advice as to any other way we can proceed with REACH application and secure reduced membership or REACH registration charges". The consortium offered to further discuss the matter in a telephone call[8] on 8 February 2013, to which the claimant responded by informing of difficulties in receiving telephone calls from abroad[9]. In the same message the claimant asked for possible price reductions for smaller companies and for accessing "only technical information".

Meanwhile, on 8 February 2013 [redacted] sought advice from the UK Competent Authority[10] and forwarded its reply[11] to the consortium for information on 11 February 2013. Furthermore, the claimant enquired to ECHA Helpdesk[12] and forwarded the information received[13] to the consortium[14] on 12 February 2013. With reference to the advice

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[1] Cf. message by [redacted] of 28 January 2013 14:50
[2] Cf. message by [redacted] of 28 January 2013 15:18
[3] Cf. message by [redacted] of 28 January 2013 17:44
[4] Cf. message by [redacted] of 29 January 2013
[5] Cf. message by [redacted] of 4 February 12:33
[6] However, ECHA notes that the amount of € [redacted] for a LoA is mentioned in the correspondence between the claimant and UK REACH Competent Authority - Cf. message of 8 February 2013 14:30
[7] Cf. message by [redacted] of 4 February 14:07
[8] Cf. message by [redacted] of 8 February 11:25
[9] Cf. message by [redacted] of 8 February 2013 12:09
[10] Cf. message by [redacted] of 8 February 2013 14:30
[11] Cf. message by [redacted] of 11 February 2013 10:38
[12] Cf. message by [redacted] of 11 February 2013 12:40
[13] Cf. message by ECHA Helpdesk of 12 February 2013 17:37

given the claimant also asked for "clarification and justification for the fees quoted and a list of the information made available and the cost per information lot".

On 15 February 2013 [redacted] formally requested[15] [redacted] in their function as representative of [redacted] to make an appeal to the consortium on behalf of the claimant in order to lower the price of SIEF membership. In the same message the claimant also insisted that "the costs of access to the information should vary according to their tonnage level, such that registrants at the [redacted] tpa will be less than those at [redacted] tpa". He also requested explanation on "what the SIEF information access fee will be, what these fees are for and the justification".

On 18 February 2013 [redacted] informed the claimant that the consortium steering committee would address the LoA costs in its upcoming steering committee meeting and at the same time stated that the company size does not determine the cost of information in a SIEF[16]. The consortium also requested information on whether the substance to be registered is [redacted] or [redacted].

Following confirmation by the claimant that the substance to be registered is [redacted][17], the consortium informed[18] the claimant on 23 April of an adjusted price for the LoA, i.e. € [redacted] "with an applied risk premium (10%) and discount (30%) for REACH only use", plus "a bank guarantee of € [redacted] to cover future costs" of tests fulfilling REACH Annexes [redacted] and [redacted]. Moreover, it was communicated in the same message that "the LoA will be discounted for those tests not required by a lower tonnage band". However, it was also stated that "the total costs are difficult to predict due to the scope of the activities and uncertainties related to testing and dossier preparation" and that "if the number of companies sharing change later, we will periodically update the cost share".

In the subsequent reply, the claimant requested[19] clarification on whether the LoA cost of € [redacted] is still the same, what the information access fee is on the basis of a tonnage band of [redacted] tpa and asked confirmation "what test work information [redacted] will be paying for within this [redacted] per year band". He also repeated his request for "a detailed cost breakdown to support or justify the fees quoted".

Replying to this email[20], the consortium confirmed "that the current estimated costs are for both the [redacted] t/yr as well as for the [redacted] t/yr". He also provided a table with the overview of expected costs and explained that the estimated "other costs" of € [redacted] included in the total of € [redacted] cover technical services, consortium and financial management, technical committee expenses and meeting expenses.

Following a further request by the claimant[21], in its response on 26 April 2013 the consortium also claimed[22] that as testing is still on going, no list of test results can be confirmed, however, the dossier would contain "Annex [redacted] data requirements, excluding any possible information requirements for [redacted]".

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[14] Cf. message by [redacted] of 12 February 2013 17:55
[15] Cf. message by [redacted] of 15 February 2013 11:43
[16] Cf. message by [redacted] of 18 February 2013 11:31
[17] Cf. message by [redacted] of 18 February 2013 10:50
[18] Cf. message by [redacted] of 23 April 2013 09:18
[19] Cf. message by [redacted] of 23 April 2013 11:52
[20] Cf. message by [redacted] of 23 April 2013 14:41
[21] Cf. message by [redacted] of 23 April 2013 16:13
[22] Cf. message by [redacted] of 26 April 2013 09:20

On 26 April 2013 the claimant reemphasised[23] his inability to pay € [redacted] for a LoA as this would result in a negative cash flow for the company and expressed his intention of paying only for access to the required test results, not for any "other costs". In the same message the claimant also asked whether the LoA cost also includes "processing of [redacted]'s] application" as otherwise further expenses would be incurred for hiring a consultant to prepare and submit the dossier. The claimant also mentioned his intention to inform ECHA of his difficulties in reaching an agreement with the consortium.

Following a reply[24] from the consortium indicating that the estimate prices "can be higher can be lower, depending on several unknown figures", the claimant stated[25] that he "cannot commit to something that can be higher dependent on several unknown figures" and "cannot offer [redacted] an open check book". The claimant thus requests "a firm LoA figure and better explained details of what [redacted] is asked to pay for".

The consortium subsequently listed[26] two reasons for the uncertainty of the costs, i.e. "the number of companies actually registering the substance" and "the required tests that need to be executed".

Finally, on 26 April 2013 the claimant announced[27] as next step "a formal appeal directly to ECHA" due to the fact that the consortium is "unable to confirm a fixed cost to [redacted]" and is also "unable to confirm to [redacted] what test work is required".

The claimant submitted a data sharing dispute claim on 9 May 2013. The claim was considered complete, as confirmed in ECHA's letter to the claimant of 13 May 2013. Furthermore, ECHA asked [redacted] on 13 May 2013 for its documentary evidence, which was received on 28 May 2013.

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.

Claimant's efforts

Based on the communication between the parties, ECHA considers that [redacted]. has made every effort to reach an agreement with the existing registrants on the sharing of data under fair, transparent and non-discriminatory conditions.

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[23] Cf. message by [redacted] of 26 April 2013 10:40
[24] Cf. message by [redacted] of 26 April 2013 14:29
[25] Cf. message by [redacted] of 26 April 2013 13:50
[26] Cf. message by [redacted] of 26 April 2013 15:00
[27] Cf. message by [redacted] of 26 April 2013 15:12

The claimant started the negotiations sufficiently early. He made contact with [redacted] in January 2013. This was 4 months [redacted]. It is fair to assume that the parties could have agreed within these 4 months. The submission of the dispute was also not pre-mature, as the last e-mails show that the negotiations had reached a standstill, because the parties had exchanged their arguments on the price of the LoA and were not willing to move away from their positions. ECHA expects that SIEF members negotiate the sharing of data and related costs by replying to the messages of the other party in a timely manner, taking up their arguments and concerns and replying and asking relevant questions as precisely as possible to make sure that the negotiations move ahead. During the 4 months of negotiations, the claimant has kept the negotiations going by replying to the consortium's messages in a timely manner.

An important element of asking relevant questions in negotiations on data sharing is inquiring about the studies that are to be shared, their cost and the number of expected registrants. After having received an offer for a LoA from the consortium, the claimant has repeatedly requested the list of the tests included in the price, a more detailed cost breakdown and further explanation as well as justification of the costs of the studies. Moreover, [redacted] disagreed with an "open check book" for unknown future costs.[28] This was an important contribution to advancing the negotiations in a constructive manner. If he would have received a reply to this question, the parties could have discussed the necessary studies and the appropriate method of calculating the costs. Thus, the negotiations could possibly have been successful.

Existing registrants' efforts

The consortium on behalf of the existing registrants did not make *every effort* to reach a *fair, transparent and non-discriminatory* agreement.

ECHA expects the existing registrants to act in an informative, transparent and responsive manner towards potential registrants, particularly if the potential registrants have not been part in the previous decision-making process. The consortium made some efforts to reach agreement with the claimant providing[29] a cost breakdown of the LoA to the claimant. However, the consortium failed to answer the claimant's questions[30] on which tests are included in the price, to provide a more detailed cost breakdown and further explanation as well as justification of the costs of the studies. Providing this information when requested is a necessary part of negotiating the sharing of data and their costs. Without a common understanding of the studies subject to the discussion and the calculation of their price, the parties cannot find an agreement on the sharing of the data and their cost. Where the existing registrants refuse to provide a list of the studies included and the calculation of their cost, they show a lack of effort and make it impossible to reach a *fair, transparent and non-discriminatory agreement.*

Moreover, the demands of the Consortium were obviously discriminatory. The consortium confirmed in its message dated 23 April 2013 that the Letter of Access cost of € [redacted] does not vary between tonnage bands [redacted] tpa and [redacted] tpa.

According to Article 30(1) of the REACH Regulation, "*registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.*" By setting the same LoA price for both tonnage bands [redacted] tpa and

[28] See footnote 10, 14, 18, 20 and 24
[29] Cf. messages by [redacted] of 23 April 2013 09:18 and 14:41
[30] Cf. messages by [redacted] of 23 April 2013 16:13 and 26 April 2013 10:40

[redacted] tpa, the existing registrants, represented by the consortium, disregarded Article 30(1) and demanded a method of cost sharing that discriminates against registrants at the [redacted] tpa tonnage band.

Conclusion

[redacted] has 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] 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 cost, provided they make the full study report available, which shall be enforceable in the national courts.