ECHA
EUROPEAN CHEMICALS AGENCY

CONFIDENTIAL

03 -04- 2014

[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-[redacted]

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 [redacted] submitted as a representative of you and 5 other Claimants ('the Claimants') on 23 December 2013 regarding the failure to reach an agreement on data sharing under Article 30(3) of the REACH Regulation with the existing registrants of [redacted] (EC number [redacted]), represented by [redacted] ('the Existing Registrants').

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 provided by the Claimants was considered complete and appropriately documented, as indicated in the communication ECHA sent to Claimants' representative on 27 January 2014. ECHA received documentation on the negotiations from the Existing Registrants' representative on 7 February 2014. ECHA, however, noticed inconsistencies with regard to the messages of 14 November, 21 November and 5 December 2013 as provided by the parties. In order to clarify the inconsistencies, ECHA contacted both parties by telephone. After having spoken to both parties and having received clarifications from the Existing Registrants on 25 February and from the Claimants on 26 February, the inconsistencies were resolved. ECHA 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 to grant you the permission to refer to the information you requested from the Existing Registrants represented by [redacted]

The detailed justification is set out in the **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 of the REACH Regulation) and must respect any property rights covering the information. Hence, 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 purpose of this claim.

Please follow the instructions in **Annex III** on how to use the information provided 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 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 for vertebrate animal data and only among SIEF participants. If you need to complete your dossier with studies not involving vertebrate animals and you have not been successful in reaching an agreement with the other parties 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 obtain data or you perform these studies either on your own, or together with other potential registrants facing similar difficulties. Additionally, 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 not prove possible[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 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 reference number in any correspondence in relation to this decision.

Yours faithfully,

[redacted]

Geert Dancet
Executive Director

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

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

Annex I to decision DSH-30-3-D-[redacted]2013-[redacted]

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 the Claimants represented by [redacted] (hereinafter referred to as "the Claimants") and the existing registrants of [redacted] represented by [redacted] (hereinafter referred to as "the Existing Registrants"), under Article 30(3) of Regulation (EC) No 1907/2006 (hereinafter "REACH Regulation").

This objective and contradictory assessment takes into account the entire negotiation process between the two parties, based on the information provided by the Claimants and the Existing Registrants.

Based on this information, ECHA has decided to grant the Claimants permission to refer to the studies relating to the endpoints requested from the Existing Registrants.

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.

As a preliminary comment, ECHA notes that the representative of the Claimants regularly informed the Existing Registrants of new potential registrants, on whose behalf he was negotiating.[1] The Claimants were mentioned in the communications of 18 June, 14 November and 21 November as well as 5 December 2013.[2] The documentation submitted shows that the Existing Registrants never objected to the information that the Claimants would join the group. They accepted the fact that the negotiations cover the Claimants as well. It also facilitated their negotiations to have one counterpart, who spoke on behalf of several Claimants. In their message of 12 December 2013, they explicitly acknowledged the Claimants[3]. This is particularly illustrated by their assertion that *"in view of the fact that you – according to your statement – represent 74 Greek companies ... we see ourselves ... in the position to recalculate the price of the LoA on this particular basis."* To implement this, they requested a written confirmation from each claimant that he would join the joint submission and continued: *"Currently the number of potential registrants can be estimated at 175 (including the participants of the joint submission). On this basis the price for the LoA* [Letter of Access] *would increase enormously."* The Existing Registrants obviously meant that the price per registrant would decrease enormously, when 175 registrants share the costs instead of 101.[4]

[1] Cf. the Claimants' e-mails of 18 June, 7 October 2013, 25 October, 29 October, 14 November, 21 November and 5 December 2013

[2] ECHA notes that all Claimants were included in the communications dated 21 November and 05 December 2013

[3] ECHA notes that 74 potential registrants were acknowledged. Not all of them are claimants of this dispute

[4] They already addressed this significant decrease in their message of 23 June 2013.

In addition, ECHA also notes that the parties initially discussed the best way to present the substance identification in the dossier.[5] However, this difference in understanding was finally not a hindrance to finding an agreement on the sharing of the data and its cost.

Beside these considerations, ECHA considers that the most contentious part of the negotiations concerns the transparency of the cost sharing mechanism. More specifically, the Existing Registrants are free to set up the cost sharing mechanism, as long as it is fair, transparent and non-discriminatory. Hence, the Existing Registrants must disclose the calculation behind the cost sharing mechanism on request. The level of detail to which the mechanism is described depends on the individual case and the Claimants' request.

Based on the information provided by both parties, ECHA has concluded that the Existing Registrants did not make every effort to reach an agreement on the sharing of data and the related costs in a fair, transparent and non-discriminatory way. To the contrary, their negotiations were vitiated with a manifest lack of transparency as regards the overall costs of the dossier. This manifest lack of transparency cannot be offset by the Existing Registrants' efforts to accommodate some of the Claimants' requests, such as taking the difficulties of SMEs into account, e.g. by allowing micro and small companies to pay in instalments, or by dividing the total costs by the total number of registrants.

In the case at hand, the Existing Registrants have calculated the overall cost for the preparation of the dossier and divided it by the number of total registrants in the Joint Submission. The Existing Registrants also agreed to divide the total costs by a number of registrants that includes the Claimants. In this case, the cost sharing mechanism is a simple division, where the total costs represent the dividend, the number of registrants is the divisor, and the cost per company is the quotient. It is correct and consistent to include the Claimants in the divisor.

Such initiative does not, however, relieve the Existing Registrants from their obligation to "*make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way*", pursuant to Article 30(1).

More specifically, in the case at hand, the Existing Registrants explained to the Claimants that the total costs were made up of dossier testing costs, strategy costs, administration costs and so-called individual costs. The share of the total costs that falls into each of these categories was explained. When the Claimants requested an explanation for the strategy cost, the administration costs and the individual costs, however, the Existing Registrants did not provide an explanation of how they had reached the sums. This amounts to a breach of the obligation to make every effort to reach an agreement on the sharing of data in a transparent way.

ECHA considers that when a detailed justification of specific aspects of the costs is requested by the Claimants for the sake of transparent cost sharing, the Existing Registrants could not ignore that request and simply decrease the cost per registrant by increasing the number of beneficiaries of the data.

On 30 August 2013 the Claimants[6] asked the Existing Registrants, amongst others, "*1. To confirm the sharing cost and the expected reimbursements 2. The structure of related costs.*" This was the first time the Claimants requested an explanation of the share of cost proposed by the Existing Registrants. Where parties in data sharing negotiations try to find a common understanding and agreement on the cost of data sharing, it is a necessary first

[5] Cf. emails from the Existing Registrants and the Claimants of 23 June, 28 June, 27 August, 9 October and 25 October 2013.
[6] Cf. the Claimants' email of 30 August 2013.

step to ask how the price was calculated. Where a claimant does this, the Existing Registrants should provide a reply that is sufficient to clarify how the price was calculated and dispel the concerns of the claimant, so that the agreement can be based on a common understanding of the costs behind the data.

On 2 October 2013[7] the Claimants requested the Existing Registrants to provide *"the total costs of the dossier, a breakdown cost per endpoint, [...] expected reimbursements."* With this request, the Claimants further detailed their previous request for an explanation of the "structure of the related cost". An explanation of the total cost and an explanation of how the costs are distributed over the endpoints is important for the parties to have a common understanding of the cost sharing mechanism. 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.

The Claimants received no reply to their request. In their replies of 2 October and 9 October 2013, the Existing Registrants addressed other issues, such as their test procedure for [redacted], but did not provide the requested explanation on the cost. Pending a reply on this issue, the Claimants sent those same questions again on 7 October, 10 October, 21 October, 25 October 2013 and once more on 14 November 2013. In this latest email, the Claimants provided a list of 14 endpoints and asked explicitly for the cost of the data for each of these endpoints.

In their response the same day, the Existing Registrant provided the Claimants with a cost breakdown. It details the data costs per endpoint, as requested by the Claimants. It also contains basic information on the organisation of the joint submission and a mentioning of other costs relating to the joint submission, i.e., strategy costs of [redacted] EUR, administrative costs of [redacted] EUR and "individual costs of the CPO" (Contractual Partner Organisation) of [redacted] EUR. They also offered the possibility for micro and small companies of paying the price of the Letter of Access in instalments.

On 20 November[8], the Claimants replied to the Existing Registrants with follow-up questions requesting more detailed information on some elements in the cost breakdown. In particular:

- they asked implicitly whether future tests envisaged in testing proposals had already been paid for, because they appeared in the cost breakdown;
- they asked explicitly for a clarification of what is covered by strategy costs and for the tasks carried out, timesheets etc. to justify the overall amount for strategy costs (questions 12, 13 and 14);
- they asked explicitly for a clarification of the administration costs and how they are structured, taking into account registrants are charged individually for their questions (question 15);
- they asked explicitly whether the cost of administration has already been paid to the Existing Registrants (question 16);
- they asked explicitly for a breakdown of the individual costs of the CPO (question 18);

[7] Cf. the Claimants' email of 02 October 2013.
[8] Cf. the Claimants' email of 20 November 2013.

- they asked explicitly whether there are any administrative, strategy or individual costs that have not yet been mentioned (question 20);

- they asked explicitly how costs were spilt between registrants at different tonnage bands (question 21); and

- they asked explicitly how costs were revised in the past years (question 22).

The Existing Registrants did not reply to this request. In the meanwhile, the Claimants sent an email dated 5 December, in which they refer to their questions of 20 November 2013. They also asked for offers, invoices and copies of bank transferring documents to substantiate the [redacted] EUR to be paid to the CPO. They point out that they have offers from several laboratories that can carry out the same physicochemical tests for less than half the price that the Existing Registrants had entered in the cost breakdown. Finally, if the Existing Registrants cannot reply to their answers, they ask for *"the final cost for taking only the Toxicological and Ecotoxicological properties [...] or at least the cost for the tests in Mammalians"* in order for them *"to opt-out for the Physicochemical properties and several administration costs"*. Furthermore, the Claimants expressed that they are still willing to *"to submit our dossiers as members of the Joint submission of the substance [redacted]"*.

On 12 December 2013, the Existing Registrants requested[9] that each Claimant submit a binding confirmation that they would join the Joint Submission. Based on potentially 175 registrants, the Existing Registrants promised to recalculate the costs and expected a significant change of the price of the Letter of Access. It is understandable that they requested a written confirmation that all Claimants participate in the Joint Submission. However, they did not reply to any of the questions on the administrative cost, on future costs, on individual costs of CPO members or on strategy costs.

In their reply[10] the following day, the Claimants repeated their questions of 20 November 2013. They also pointed out that they have a right to know the reason for the amount of the expenses made so far and the budgeted expenses in order to agree on a fair sharing of data. They stressed that *"the cost of the LoA is not only a question of how many members participate in the joint submission, but the dossier cost itself"*, and pointed out that they do not consider the Existing Registrants' approach transparent.

Pending a further reply, the Claimants lodged the data sharing dispute to ECHA on 23 December 2013. At this point in time, the Existing Registrants had had more than one month to reply to the Claimants' questions of 20 November. Considering that the Existing Registrants' had already summed up the various costs that were the subject of these questions, the necessary information to reply to the questions should have been readily available to them. If they were not, they should have replied to the Claimants and told them when they are able to reply.

Based on the communication between the parties, ECHA concludes that the Existing Registrants have not made every effort to reach an agreement on the sharing of data and costs in a transparent manner. More specifically, they ignored the Claimants' repeated requests for more detailed information on the strategy costs, future costs, administration costs and individual costs. The Claimants' questions in this regard were relevant and reasonable, given that these specific aspects of the costs made up the largest part of the overall costs that were to be shared among all registrants, including the Claimants.

[9] Cf. the Existing Registrants' emails of 12 December 2013.
[10] Cf. the Claimants' emails of 13 December 2013.

The Existing Registrants' proposal to share the overall costs by the total number of registrants, including the Claimants, does not remedy this shortcoming. Even if it was proposed that the total costs would be divided between all the registrants, it was legitimate for the Claimants to obtain clarifications on the nature of these total costs, because the individual shares are eventually dependent on the total costs. By failing to provide the requested clarifications, the Existing Registrants breached their obligation of transparency and deprived the Claimants from the opportunity to challenge the financial demand of the Existing Registrants. Providing this information would have been a necessary effort to ensure progress of the negotiations about an agreement on data sharing.

Consequently, in accordance with Article 30(3) of the REACH Regulation, the Claimants shall be granted a permission to refer to the relevant vertebrate animal studies that were negotiated with the Existing Registrants.