

Helsinki, 24 -01- 2010

[REDACTED]

EC number: [REDACTED]  
Reference number: DSH-30-3-[REDACTED] 2010

Decision No: DSH-30-3-D-[REDACTED] 2010

**DECISION ON REQUEST FOR PERMISSION TO REFER TO INFORMATION, UNDER  
ARTICLE 30(3) OF REGULATION (EC) No 1907/2006**

In accordance with Article 30(3) of Regulation (EC) No 1907/2006 ("the REACH Regulation"), the European Chemicals Agency (ECHA) has examined the information you [REDACTED] provided on 9 November 2010, regarding failure in reaching an agreement on data sharing concerning [REDACTED] (EC [REDACTED]) with the existing registrants, members of the [REDACTED] including their lead registrant, [REDACTED] represented by [REDACTED]

The information you provided was considered complete and appropriately documented, as indicated in our letter to you dated 18 November 2010. ECHA received information from the [REDACTED] within the set deadline and conducted a contradictory assessment of the information provided by both parties.

As a result of this assessment according to Article 30(3) covering the exchange of communication up to the date of the complaint, ECHA has decided to **not grant you permission to refer to the information requested to fulfil your registration purposes:**

[REDACTED] and information requirements as listed in Annexes [REDACTED]

On the basis of the information provided by both you and the other party, ECHA concluded that, pursuant to Article 30(1) of the REACH Regulation, every effort to reach an agreement on the sharing of the costs in a fair, transparent and non-discriminatory way, has not been made.

More specifically, ECHA took its decision on the basis of the following reasons:

- In its correspondence with the [REDACTED] did not challenge the conditions of the transparency of the data sharing conditions. Indeed, the [REDACTED] replied promptly to the emails sent by [REDACTED] with a description of the procedure used to calculate the costs of becoming a member of the consortium and with the approximate cost for [REDACTED] to become a member. The cost of a letter of access was given on 19 July 2010, and the indicative cost of joining the consortium

was given on 29 July 2010.<sup>1</sup> Although these costs were provided several months after the first request, [REDACTED] still had three months before the applicable registration deadline to challenge the offer or to request further clarifications.

- [REDACTED] requested to "take a closer look at the calculation" of the costs of joining the [REDACTED]. The [REDACTED] declined to "give a full overview at this point of the negotiations", but provided some details.<sup>3</sup> Although [REDACTED] raised concerns in its claim to ECHA as to the lack of information on the costs of joining the [REDACTED] ECHA notes that [REDACTED] has not requested any further clarification directly to the [REDACTED]. Concerning the distribution of the costs of purchasing a letter of access, ECHA notes that [REDACTED] has not requested any clarification or raised concern as to the transparency.
- Based on the available information, [REDACTED] has stopped corresponding with the [REDACTED] after it received confirmation of the cost of a letter of access on 27 August 2010. Nevertheless, on 10 November 2010, [REDACTED] lodged a data sharing dispute procedure to ECHA.
- Concerning the fairness and the non-discriminatory nature of the cost sharing conditions, ECHA took note of the argument provided by [REDACTED] in its claim to ECHA that the share concerning essential studies (estimated by [REDACTED] at [REDACTED]) is disproportionate, in so far as the [REDACTED] should comprise, according to [REDACTED]. However, ECHA did not identify in the correspondence provided by the parties any claim in that respect directly submitted by [REDACTED] to the [REDACTED]. Therefore, it cannot be considered that [REDACTED] has challenged this cost sharing with constructive arguments, which might have made the [REDACTED] change its initial offer to share data.
- Based on the above, ECHA considers that [REDACTED] cannot hold the other party responsible for the failure to reach an agreement on the sharing of the costs in a fair, transparent and non-discriminatory way, if it has not itself made every effort to reach such agreement. As a result, ECHA encourages all the parties to continue negotiating.

Besides the result of its assessment, ECHA would like to make some general observations in order to facilitate a future agreement.

- ECHA reminds all registrants that, Article 30 imposes on data owners, whether registrants gathering in a consortium or individual registrants, to make every effort to reach an agreement on the sharing of data in a fair, transparent and non discriminatory way.
- Making every effort in reaching an agreement requires both 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.

<sup>1</sup> Respectively, emails from the [REDACTED] to [REDACTED] of 17.07.2010 and 29.07.2010.

<sup>2</sup> Email of 22.07.2010 from [REDACTED] to the [REDACTED].

<sup>3</sup> Emails from the [REDACTED] to [REDACTED] of 22.07.2010.


- Article 30 of the REACH Regulation requires registrants to only share the costs necessary to satisfy their registration requirements. Accordingly, if existing registrants rely on read-across to develop different dossiers covering several categories of substances, they cannot impose on a subsequent registrant to purchase data used for the registration of categories of substances that he does not manufacture or import, unless they justify the relevance of the data concerned. In any case, the subsequent registrant should only contribute to the cost of the category of substances including the substance he has to register.
- Finally, Article 11 of the REACH Regulation imposes on multiple registrants of the same substance to submit one joint submission comprising the shared information. The option for opt-out, as described in Article 11(3), may only apply to individual studies and not the entire joint submission.

ECHA hopes that these observations will help the parties in the present case to continue the discussions in order to reach an agreement. Should you consider you have failed to reach an agreement, please note again that a data sharing dispute claim can be lodged to ECHA only as a last resort.

If you have a specific concern about the content of this message you can contact ECHA using the webform at [http://echa.europa.eu/about/contact-form\\_en.asp](http://echa.europa.eu/about/contact-form_en.asp) and then selecting the menu item 'Enquiry on specific submission to ECHA'.

In accordance with Article 30(5) of the REACH Regulation, the potential registrant or the previous registrants may appeal against this decision to the Board of Appeal of ECHA within three months of receiving notification of this decision. The procedure for lodging an appeal is described at [http://echa.europa.eu/appeals/app\\_procedure\\_en.asp](http://echa.europa.eu/appeals/app_procedure_en.asp).

Yours faithfully,



Geert Dancet  
Executive Director

Copy: 