

Helsinki, 14 -02- 2011

[REDACTED]  
[REDACTED]  
[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 REQUESTED FROM [REDACTED] 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] hereafter, [REDACTED]) provided on 1 December 2010, regarding failure in reaching an agreement on data sharing with [REDACTED] (hereafter, [REDACTED]), the lead registrant for the substance with EC number [REDACTED] ([REDACTED]).

The information you provided was considered complete and appropriately documented, as indicated in our letter to you dated 16 December 2010. ECHA received information from [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:**

All studies needed for the [REDACTED]ty band information requirements as listed in Annexes VII to X.

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.

From the available information we note that [REDACTED], acting as a lead registrant, seems to have only occasionally communicated with the SIEF participants. In that respect, the correspondence provided by the parties shows that, although [REDACTED] initially indicated its desire to be "involved" in the preparation of the dossier,<sup>1</sup> a later email explicitly asked [REDACTED] to ensure that its status is "passive".<sup>2</sup> As a result, and in the absence of information as to whether any other SIEF participant indicated their wish to be actively involved in the preparation of the dossier, ECHA cannot draw any conclusion as to the appropriateness of [REDACTED] efforts to communicate with other SIEF participants.

<sup>1</sup> Email from [REDACTED] to [REDACTED] of 27 August 2009.

<sup>2</sup> Email from [REDACTED] to [REDACTED] of 06 May 2010.

Several emails from ██████ urged the lead registrant to provide information on the cost for obtaining the right to refer to the dossier. However, the negotiations on the sharing of the costs of the joint registration dossier actually started on 22 October 2010<sup>3</sup>, when the lead registrant provided information on the costs for joint submission. From that point, ECHA notes that ██████ replied to the requests made by ██████ within a reasonable time. Nevertheless, after the actual start of the negotiations, the only concern of ██████ referred to the fact that ██████ did not inform sufficiently the SIEF participants early that some information included in the joint dossier would need to be obtained from a third party, ██████. ECHA also notes that this information was communicated on 22 October 2010, two weeks before the registration was actually submitted. The available information does not allow ECHA to determine whether ██████ would have been in a position to provide this information earlier. This information was dependent on the position of the third party. In addition, irrespective of the fact that ██████ considered that they were informed too late, the information provided does not show that ██████ made any effort to initiate negotiations with ██████ within the remaining weeks up to the registration deadline. Concerning the content of the negotiations, ██████ has raised several arguments in various emails.<sup>4</sup> ECHA notes that ██████ has commented on each of these claims.

Firstly, concerning risk premiums, ECHA notes that ██████ invoked the practice applicable in other SIEFs without demonstrating objectively why such a premium would be fair. ██████ could also objectively argue for instance, that a risk premium would be only justifiable when the outcome of a testing involves an actual risk (e.g. testing failure).

Secondly, concerning the equal distribution of the study costs between the two registrants; ECHA understands that only ██████ and ██████ were interested in submitting a dossier by December 2010. A distribution of costs for the studies based on an equal share is in line with the REACH regulation and does not seem manifestly unfair. This is particularly true if the distribution of costs will be recalculated to take account of future registrants, resulting in ██████ being reimbursed for the payment provided in excess.

Beyond this concern, ECHA understands that ██████ actually disagreed as a matter of principle with the data and cost calculation formula selected by ██████. More specifically, ██████ argue that it has not received sufficient information to assess the relevance, reliability, quality and costs of the data selected by ██████<sup>5</sup>. ECHA notes that the information that would allow that determination was considered valuable and confidential assets by the lead registrant. ██████ therefore proposed to disclose that information after the signature of the SIEF agreement, including a confidentiality clause.<sup>6</sup> ██████ declined to sign the SIEF agreement and offered on 25 November 2010 to provide a separate confidentiality agreement. ECHA does not have information showing that a confidentiality agreement was eventually provided by ██████. In addition, ██████ refused to sign the SIEF agreement on the basis that the REACH Regulation does not impose that approach. Although it is correct that the legislation does not impose concluding a SIEF agreement, it leaves to all the parties the exclusive competence to organise their relationship. It also requires them to make every effort to reach an agreement on data sharing. Setting out a contract between potential registrants in a SIEF may show the efforts of the parties to reach an agreement.

<sup>3</sup> Email sent from ██████ to the SIEF participants of 22 October 2010.

<sup>4</sup> Email from ██████ to ██████ of 31 October 2010, 18 November 2010 and 19 November 2010.

<sup>5</sup> Email from ██████ to ██████ of 19 November 2010.

<sup>6</sup> Email sent from ██████ to ██████ of 22 November 2010.

Thirdly, [REDACTED] also claims that the rights to the studies are restricted and should therefore result in a smaller share of the costs to be paid. We understand that [REDACTED] refer to the absence of transfer of ownership of the studies. It is not clear from the available information if and how many studies are actually owned by [REDACTED], for which it could decide to share the ownership. In addition, to the extent that [REDACTED] would receive a refund from future registrants for the studies, [REDACTED] would benefit from one of the main advantages of ownership. However, [REDACTED] has not made sufficient effort to justify its claim that the absence of sharing of ownership should result in a lower share of costs.

Fourthly, [REDACTED] holds [REDACTED] responsible for the conditions of sharing the costs for a study i.e. [REDACTED] to be negotiated with [REDACTED]. ECHA notes that [REDACTED] is not entitled to negotiate costs for this study. [REDACTED] claims that the relevant endpoint could have been fulfilled by using other studies including publicly available studies. ECHA would like to clarify that Article 11(3) of the REACH Regulation allows a registrant to submit information separately if he disagrees with the lead registrant on the selection of this information or if it would be disproportionately costly to submit this information jointly. In any case, the justification provided to support the other data submitted shall be scientifically valid.

Finally, [REDACTED] (acting as an only representative) holds [REDACTED] responsible for not having contacted them or their client in order to obtain certain data their client owns. Contrary to what [REDACTED] argues, Article 30 of the REACH Regulation does not oblige a lead registrant to inquire if any data is available from other SIEF participants. The obligation to inquire in the SIEF only applies before testing is carried out in order to meet an information requirement and only if the relevant study involves testing on vertebrate animals. Provided that testing has not been conducted, which ECHA does not know from the available information, [REDACTED] has therefore not breached its obligations. In addition, pursuant to Article 11(3) of the REACH Regulation, [REDACTED] is also allowed to submit information separately if it would be disproportionately costly to submit this information jointly, provided that it is able to provide adequate scientific justification in support of the data submitted.

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. 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 companies, to make every efforts 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.

In cases where existing registrants decide to submit a dossier without the assent of other SIEF participants, the unilateral selection of data and of the cost sharing methodology is likely to create legitimate suspicions from other registrants as to the fairness of the compensation requested. Those registrants therefore bear a specific responsibility in providing sufficient and relevant information justifying their choices. This applies not only to the scientific basis for selecting the data, but also to the resources invested in the preparation of the dossier, increments (such as risk premium and other surcharges) or any other cost for which the existing registrants claim compensation.

Article 30 of the REACH Regulation requires registrants to only share the costs necessary to satisfy their registration requirements. Accordingly, each registrant shall be given the opportunity to assess the relevance of the data for the dossier. Each subsequent registrant may also decide to submit some information separately, in accordance with Article 11(3) of the REACH Regulation, if he disagrees with the selection of data or if it would be disproportionately costly for him to submit the data jointly. In this case, the justification provided to support the data submitted separately shall be scientifically valid.

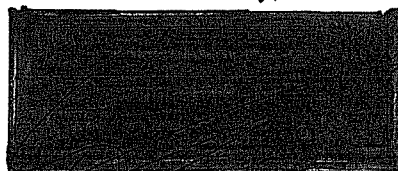
In addition, if existing registrants rely on read-across to develop different dossiers covering several categories of substances, they cannot impose on a subsequent registrant to purchase data used for the registration of categories of substances that he does not manufacture or import, unless they justify the relevance of the data concerned. In any case, the subsequent registrant should only contribute to the cost of the category of substances which include the substance he has to register.

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 fail 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

Cc: 