ECHA
European Chemicals Agency

Helsinki, 22 -12- 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 REQUESTED FROM THE MEMBERS OF THE [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 (for [redacted]) provided on 17 October 2010, regarding failure in reaching an agreement on data sharing under Article 30(3) of the REACH Regulation with the existing registrants, [redacted] including their lead registrant, [redacted] regarding the substance with EC number [redacted]

The information you provided was considered complete and appropriately documented, as indicated in our letter to you dated 27 October 2010. ECHA received information from the lead registrant, [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 from the existing registrants [redacted] including their lead registrant [redacted] as represented by [redacted] (hereafter, [redacted]). More specifically, the requested information refers to:

[redacted] band 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, have not been made.

More specifically, ECHA took its decision on the basis of the following reason(s):

During the negotiations, you raised arguments relating to the fairness of the data sharing conditions and their transparency.

Concerning the fairness of the data sharing conditions, you have questioned on several occasions the conditions applicable to different aspects of the data sharing scheme.[1] More specifically, you challenged the fact that the scheme does not provide for separate conditions for data required for substances in the [redacted] You range or for [redacted] pointed out that it would be unfair to not have specific rules for these categories. Besides, we understand from your correspondence that the data requirements actually applicable to your company relate to a different category, i.e. the [redacted] tonnage band. We also note that you have only informed [redacted] of your actual data requirements late in the negotiations.[2] Although the argument referring to other data requirements may possibly be claimed by the registrants to which these requirements apply, we note that you have not demonstrated to [redacted] to which extent this aspect would affect directly and individually your situation. Accordingly, without prejudging the relevance of that argument for other SIEF participants, based on the available information, this aspect should not have prevented your company from reaching an agreement on the sharing of the data.

Concerning the transparency of the data sharing conditions, you claim that the conditions of reimbursement of the study owners and the cost of future [redacted] activities are not sufficiently clear.[3] In relation to the reimbursement of the study owners, we note that [redacted] has provided you with details on the nature of the costs with numerical examples. Furthermore they have attached three license fee waiver agreements (as proposed in an earlier communication), together with a spreadsheet of study costs (calculated on the basis of the historical value). [redacted] also provided numerical data to clarify the efforts made by the [redacted] in order to limit the cost of a letter of access for the future registrants. In this regards, [redacted] has fulfilled its obligation to make every effort of transparency. You then challenged the fairness of the approach described by [redacted] by invoking in general terms that this cost sharing scheme comprises "*studies not required, redundant studies and studies with low reliability*".[4] We would like to point out that several provisions in REACH explicitly require registrants to collect and/or to submit all available and relevant information.[5] Accordingly, all the data that is necessary to demonstrate the safe use of a substance shall be reported, this may include several studies for each endpoint. ECHA notes that you have not made any specific arguments questioning the scientific justification used to select data for any particular endpoint. Rather, ECHA considers that a generic statement that studies are not required and that other consortia apply other conditions are not, as such, sufficient to challenge the fairness of the reimbursement of study owners.

You also challenge the allocation of costs to the funding of future [redacted] activities. Indeed, we note that [redacted] explains that part of the revenues of the sharing of data shall cover future costs related to other regulatory work and administration between 2010 and 2022. This refers to [redacted] activities relating, notably, to Member States proposals to re-classify the substance and to assess its risks in view of adopting possible measures.[6] Article 30 of the REACH Regulation requires registrants to only share the costs necessary to satisfy their registration requirements. Accordingly, ECHA believes that the cost of future activities of [redacted] not necessary to satisfy the registration requirements, should in principle not be shared with registrants which are not part of that [redacted] However, if future work may exceptionally be

1 Your emails of 14 September 2010, 17 September 2010 and 01 October 2010.
2 Your email of 17 September 2010, corresponding to your seventh email out of ten messages.
3 Your emails of 17 September 2010 and 01 October 2010.
4 Your email of 01 October 2010.
5 See Recital 17, Article 12(1) and the first paragraph and last sentence of Annex VII of the REACH Regulation.
6 Email from [redacted] on 17 September 2010.

necessary to satisfy registration requirements, the conditions of fairness, transparency and non discrimination shall be met. These conditions should include, notably, that the costs are actually transparent, that they relate to future activities which are not hypothetical, which these other registrants will clearly benefit from and the cost of which they agree to share.

Nevertheless, we note that your argument was raised on the last day of your correspondence, before your complaint to ECHA was lodged. We are concerned that [redacted] and the [redacted] did not have the opportunity to address this valid concern. Based on this circumstance, as well as on the complexity of data sharing negotiations in general and the time still available for you before you are compelled to register (until 1 June 2013), ECHA considers that both parties still have an opportunity to make efforts to reach an agreement on the sharing of the costs of data in a fair, transparent and non-discriminatory way.

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

If requested, previous registrants shall provide scientific justifications of the approach followed in the selection of data that is necessary to demonstrate the safe use of the substance, especially if potential registrants have asked without success to be involved in the selection of that data. In that respect, guidance on the selection of all available and relevant data can be found in the "Practical Guide 4: How to report data waiving".[7]

Making all the efforts in reaching an agreement requires both the potential and the 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 is unclear, invalid or incomplete, it is the responsibility of the recipient to challenge that answer, by addressing proactive, clear and precise questions to the sender and not by commenting the response with general statements.

Each party shall give reasonable time to the other for providing appropriate answers to its questions.

Moreover, data sharing dispute procedures must be initiated only as a last resort, when all the possible efforts and arguments have been exhausted.

Finally, ECHA reminds both parties that Articles 30 and 11 of the REACH Regulation impose on multiple registrants of the same substance to share certain information and 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.

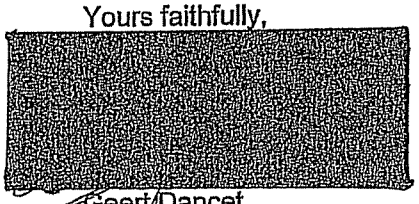
Consequently ECHA advises that you continue the discussions in order to reach an agreement.

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* and then selecting the menu item 'Enquiry on specific submission to ECHA'.

[7] Section 2.1.3 « Availability of multiple pieces of information » in Practical Guide 4 available on the following link : http://echa.europa.eu/doc/publications/practical_guides/pg_report_data_waiving.pdf

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.

Yours faithfully,



Geert Dancet
Executive Director

Cc. [redacted]