

Helsinki, 24 -01- 2011

[REDACTED]

EC number: [REDACTED]
Reference number: [REDACTED]

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

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

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 16 November 2010, regarding failure in reaching an agreement on sharing data on the substance with EC number [REDACTED] with the existing registrants, [REDACTED] including their lead registrant, [REDACTED] represented by [REDACTED].

The information you provided was initially considered incomplete and not appropriately documented, as indicated in our communication to you dated 18 November 2010. In a reply to our letter, [REDACTED] acting on behalf of [REDACTED] on the occasion of the claim to ECHA and during the negotiations, provided on 22 November 2010 a very brief description of the efforts to reach an agreement.

Following your correspondence, due to the short time to perform an assessment of your claim before the registration deadline, ECHA granted your company on 26 November 2010 a temporary permission to proceed with the registration of the substance without the full data set, pending the assessment of your claim. In this communication, ECHA reiterated the "concern that the evidence you have provided was still very limited". ECHA also informed you of the procedure, i.e. ECHA "has also given [REDACTED] the lead registrant for the substance of concern, the opportunity to provide information on dispute." Nevertheless, ECHA did not receive any information from [REDACTED] within the set deadline and, therefore, conducted the assessment of your claim on the basis of the information you provided.

Additionally, ECHA noticed that you did not submit a registration dossier prior to the 1 December 2010 deadline. Hence, in our communication of 21 December 2010, we indicated to you that we "noticed that you have not submitted your dossier prior to the [1 December 2010] deadline." You have also been informed on possible legal consequences regarding defaulting registrants.

Lately, on 14 January 2011, you submitted further information consisting of correspondence you had with [REDACTED] on substance identification and indication of cost of the Letter of Access, going from March 2009 up to early January 2011.

Please note that, for the current assessment, we have only taken into account the correspondence up to the date of the submission of your request to ECHA.

As a result of this assessment, ECHA has decided to not grant you permission to refer to the information requested from existing registrants, [REDACTED] including their lead registrant, [REDACTED]

All studies needed for [REDACTED] information requirements as listed in Annexes [REDACTED]

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

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

Based on the information available to ECHA, the negotiations, before the claim was lodged, were limited to one email sent on 29 September 2009 by [REDACTED] on behalf of [REDACTED] to [REDACTED] claiming that the price of the Letter of Access is high and asking several questions. These questions were relating to the transparency of the costs, the possible impact on the cost of the small size of the applicant and of the small number of identified uses.¹ We note that [REDACTED] has answered to these questions within a week, i.e. on 5 October 2010.²

Moreover, ECHA's assessment could only be limited in so far as, beside the above questions, the supporting documents submitted to ECHA did not include any evidence of detailed argumentation challenging the fairness or transparency of the cost. In addition, the supporting documents did not include any background documentation identifying the nature of the costs requested.

Finally, ECHA notes that, before submitting your claim, you have not challenged the position of [REDACTED] with constructive arguments, which might have justified [REDACTED] to share data. In the absence of further information in the dossier and of any argument from your side, the position of [REDACTED] does not seem to be manifestly inappropriate.

Based on these circumstances, as well as considering the complexity of data sharing negotiations in general and the time that was still available for you before the registration deadline, ECHA considers that you have stopped the negotiations prematurely without making every effort to reach an agreement, as requested pursuant to article 30(1) of the REACH Regulation.

Consequently, ECHA advises that you continue the negotiations to reach an agreement with existing registrants, [REDACTED] including their lead registrant, [REDACTED]

¹ Email sent from Intertek to Dr Knoell Consult GmbH of 29.09.2010

² Email sent from SAS for REACH consortium to Intertek of 05.10.2010

Besides the result of its assessment, ECHA would like to make some general observations in order to facilitate a future agreement between you and the existing registrants, [REDACTED]

ECHA reminds all registrants that, Article 30 imposes on data owners, whether registrants gathering in a consortium or individual companies, 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. The argumentation challenging the position of each party needs to be exchanged between those two parties directly and not only with ECHA.

Article 30 of the REACH Regulation requires registrants to only share the costs necessary to satisfy their registration requirements.

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 to the entire joint submission.

ECHA hopes that these observations will help the parties in the present case and advises both parties 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 claims 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 and then selecting the menu item 'Enquiry on specific submission to ECHA'.

In accordance with Article 30(5) of the REACH Regulation, you 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 sincerely,

[REDACTED]

Geert Dancet
Executive Director

Copy: [REDACTED]