

Helsinki,

05-03-2012

[REDACTED]

EC number: [REDACTED]

Reference number: DSH-30-3-[REDACTED]-2011

Decision No: DSH-30-3-D-[REDACTED]-2011

**DECISION ON REQUEST FOR PERMISSION TO REFER TO INFORMATION
REQUESTED FROM THE REGISTRANTS AND DATA OWNERS OF [REDACTED]
[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 that [REDACTED] provided on 18 November 2011 regarding the failure to reach an agreement on the sharing of data under Article 30(3) of the REACH Regulation with the existing registrants, including the lead registrant [REDACTED] for [REDACTED] with EC number [REDACTED].

The information that [REDACTED] provided was considered complete and appropriately documented, as indicated in ECHA's letter to [REDACTED] of 28 November 2011. ECHA received information from [REDACTED] but took it into account only insofar as it related to the negotiations that had taken place until 18 November 2011, the date on which [REDACTED] submitted their claim to ECHA.

Pursuant to Article 30(1) of the REACH Regulation, potential registrants and data owners are obliged to share studies involving tests on vertebrate animals. They "shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way". Hence, the submission of a data sharing dispute to ECHA should only be a measure of last resort, where the potential registrant's best efforts have failed in the light of the data owner's lack of effort. ECHA's procedure for data sharing disputes does not replace the obligation of the parties to reach an agreement and therefore autonomous negotiations. Consequently, ECHA grants a potential registrant the permission to refer to data which have previously been submitted, where it is established that the potential registrant has made every effort to reach an agreement on the sharing of the data and their costs in a fair, transparent and non-discriminatory way, where the data owner has not made every effort in this regard and where the dispute claim is thus submitted as a last resort to solve a dispute between the parties.

On the basis of the documentation supplied, ECHA has decided **not to grant permission to refer** to the information requested from the existing registrants, including the lead registrant [REDACTED]. The requested information referred to all studies needed for [REDACTED] as listed in Annexes [REDACTED] of the REACH Regulation.

ECHA notes that [REDACTED] has approached [REDACTED] more often than it has received replies from [REDACTED]. In addition, [REDACTED] has created the impression on two occasions that it would be able to supply the letter of access on the following day. The first of these was on 13 October 2011, when [REDACTED] announced its plan to send the letter of access on the following day. Also on 25 October, [REDACTED] expressed its confidence of being able to send the letter of access details and the SIEF agreement on the followings day. Both announcements were not followed up on the following day. On two other occasions, [REDACTED] has made similar statements that the letter of access cost would be planned to be ready the following week³ or that they would revert with "details" the following day.⁴ Announcing the imminent sending of the letter of access or creating the impression that other important information would be sent shortly was not an appropriate course of action for [REDACTED] where it was not able to follow up on its announcement.

Nevertheless, the documentation submitted does not establish the justification of the need, alleged by [REDACTED] to register the substance more than a year before the deadline. Although [REDACTED] claims being under pressure to submit a registration as soon as possible⁵, this allegation is not sufficient to justify urgency to conduct the negotiations. If the need to register as soon as possible would have been communicated to [REDACTED] with an appropriate justification, indeed swift action could have been expected from [REDACTED]. However, in the present case, such a need for urgency has not been justified. The fact that [REDACTED] did not supply the letter of access on the following day would not, therefore, endanger a registration in a timely manner by [REDACTED]. Indeed, the speed of the negotiations has to be considered in proportion with the necessity to submit a registration. In the present case, a year and a half remained before the registration deadline applicable to the potential registrant. As there is still ample time for the parties to reach an agreement before the relevant registration deadline, ECHA cannot consider that the information of the failure to reach an agreement was submitted as a measure of last resort.

Moreover, at the time of the submission of the data sharing claim to ECHA, the parties have not encountered any issue on which they disagreed and could not find a common understanding. The progress of the negotiations also results from the following circumstances. [REDACTED] indicated to [REDACTED] that it was discussing issues in the consortium, which would need to be resolved before letters of access were sold for the subsequent registration deadlines.⁶ The negotiations were progressing on

¹ Cf. messages by [REDACTED] of 2 August 2011, 8 August 2011, 15 August 2011, 13 September 2011, 20 September 2011, 30 September 2011, 12 October 2011, 14 October 2011, 21 October 2011, 31 October 2011, 9 November 2011 and 15 November 2011 to [REDACTED].

² Cf. Messages by [REDACTED] of 20 September 2011, 29 September 2011, 13 October 2011, 25 October 2011, 9 November 2011 and 18 November 2011 to [REDACTED].

³ Cf. messages by [REDACTED] of 20 September 2011.

⁴ Cf. messages by [REDACTED] of 9 November 2011.

⁵ Cf. messages by [REDACTED] of 30 September 2011, 9 November 2011 and 15 November 2011.

⁶ Cf. messages by [REDACTED] of 29 September and 18 November 2011 on the SIEF Agreement, message of 13 October 2011 on test results included.

Important issues, such as the costs⁷, the guidance on safe use and the CSR as part of the package⁸, the uses covered by the exposure scenarios.⁹ In addition, [REDACTED] was offered the token for the joint submission on 29 September 2011. Only if [REDACTED] would have encountered issues, on which they would not come to an agreement with [REDACTED] before the registration deadline despite their best efforts, they could have notified the failure to reach an agreement and have received the permission to refer to the relevant data.

In conclusion, ECHA advises both parties to continue the negotiations in order to reach an agreement, and to inform each party in a timely manner. In addition, ECHA wishes to insist again on the obligation of registrants to initiate data sharing dispute procedures as a last resort, i.e. only after all the possible efforts and arguments have been exhausted and the negotiations have failed.

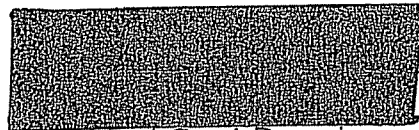
Contact

Should you need to follow up on this particular matter, please contact ECHA using the following email address: datasharing-disputes@echa.europa.eu, stating the above-mentioned EC number and the reference number in any correspondence with ECHA in relation to this decision.

Notice of Applicable Legal Remedies

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,



Jukka MALM
Director


Geert Dancet
Executive Director

Cc. [REDACTED]

⁷ Cf. messages by [REDACTED] of 29 September, 13 October and 18 November 2011.

⁸ Cf. messages by [REDACTED] of 30 September 2011 and by [REDACTED] of 13 October 2011.

⁹ Cf. messages by [REDACTED] of 13 October and by [REDACTED] of 14 October 2011.