

29 April 2013

[REDACTED]

Copy to:

[REDACTED]

Reference number: DSH-30-3-[REDACTED]-2013

**COMMUNICATION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 30(3) WITH THE EXISTING REGISTRANTS OF THE SUBSTANCE WITH EC NUMBER [REDACTED], REPRESENTED BY [REDACTED]**

Dear Mr [REDACTED],

The European Chemicals Agency (ECHA) acknowledges receipt of the information you, on behalf of [REDACTED] submitted on 05 April 2013, in relation to the data sharing dispute claim and indicating failure to reach an agreement to share data involving tests on vertebrate animals pursuant to Article 30(3) of Regulation (EC) No 1907/2006 (the REACH Regulation), with the existing registrants of [REDACTED] represented by [REDACTED].

ECHA has reviewed the documentary evidence you submitted with your claim and noted that the substance you, on behalf of [REDACTED], intend to register, is not [REDACTED], which is registered by the other party, but [REDACTED] with EC number [REDACTED].

Article 30 of the REACH Regulation strictly refers to participants of the same SIEF. This provision therefore only obliges potential registrants and existing registrants of the same substance to share the data they require for registration. Consequently, the data sharing dispute under Article 30(3) of the REACH Regulation, in the context of which ECHA may grant a registrant the permission to refer to previously submitted information, is only applicable in the relation between potential and existing registrants of the same substance. For these reasons, a dispute claim concerning data submitted for another substance is inadmissible.

**Therefore, your data sharing claim has been considered inadmissible under Article 30(3) of the REACH Regulation.** ECHA will not pursue its assessment and the data sharing dispute procedure with reference number DSH-30-3-[REDACTED]-2013 is hereby closed.

General observations to both parties

Pursuant to Article 25(1) of REACH, "in order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests".

ECHA recommends and supports the application of Article 25(1) to similar substances for read-across purposes. That way, registrants contribute to the aim set out in Recital 33 of the REACH Regulation, which promotes the "joint submission and the sharing of information on substances in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals".

Some elements, which could be taken into consideration for the negotiations are listed below:

- To break a deadlock in negotiations, parties may make an offer with the price they consider appropriate for the robust study summaries that need to be included in the registration dossier;
- If negotiations with the previous registrants (or their representative) are not fruitful, the potential registrant may consider negotiating the sharing of data directly with the data owners, as listed in the cover note attached to the claim;
- As the potential registrant will have to create a new IUCLID file for the substance and cannot copy parts of a IUCLID file into another IUCLID file, the IUCLID dossier of the other party may not be needed, but merely the data underlying it.
- Pursuant to its Recital 48, the REACH Regulation should be without prejudice to the full and complete application of the Community competition rules. Consequently, registrants must ensure that they respect Articles 101 and 102 of the Treaty on the Functioning of the European Union also when sharing data with competitors in the framework of a SIEF. Abusive practices, agreements and concerted practices are not restricted to any criterion of substance sameness, but may be prohibited in relation to different substances competing on the same market.

ECHA thus advises both parties to make every effort to reach an agreement to share the data in a fair, transparent and non-discriminatory way.

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

Yours sincerely,



Guilhem de Seze  
Head of Unit - Substance Identification and Data Sharing