

How to best conduct data sharing negotiations

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What does REACH require?

Article 30(1)

- Registrants to make **every effort** on agreeing on the sharing of information and its costs
- In a **fair**, transparent and **non-discriminatory way**

Background: Webinar from 17 January 2012:

<http://www.echa.europa.eu/web/guest/support/training-material/webinars>



Top tip 1 – every effort

- ✓ Continue the negotiations as far as possible
 - ☞ Both parties share responsibility to find an agreement
- ✓ Challenge the position of the other party with precise questions
 - ☞ ECHA will not negotiate on your behalf
- ⊘ Do not stop prematurely the negotiations and find alternative solutions
 - ☞ When considering a cost sharing model, if the number of final registrants is not clear at that stage, the registrants may also consider other compensation schemes
 - ☞ Remain proportionate, proactive and open

Top tip 2 – fair

- ✓ Give reasonable time for the other party to provide answers
 - ☞ Reasonable time should be considered in the light of the registration deadline
- ✓ Provide proportionate costs of studies according to the information requirements
 - ☞ Members are to compensate data owners (or their representatives) according the requirements linked to their own tonnage band (for 2013, no requirements for Annex X)
- ⊘ Do not lodge a claim to ECHA just one week after you initiated the negotiations
- ⊘ Do not charge costs of more substances than the one requested

Top tip 3 – transparent (1)

- ✓ Provide scientific justification of the approach followed in the selection of data/ cost sharing model
 - ☞ Especially if subsequent registrants were not consulted
 - ☞ Especially if some data was not included
- ✓ Specify the exact nature of the information requested from the data owner
 - ☞ List of all the endpoints instead of “relevant data” or “my deadline is 2013”
- ✓ Provide the procedure to calculate the costs for becoming a SIEF member

Top tip 3 – transparent (2)

- ✓ Any concern must be expressed to the other party involved
 - ☞ Challenging the position of the other party has to be communicated and justified directly to that party and not only to ECHA

- ⊘ Do not claim the costs are too high without clearly requesting what you wish to know
 - ☞ Split of costs studies vs. administrative costs, number of studies per endpoints, number of uses, number of SIEF members, ...

Top tip 4 – non-discriminatory

- ✓ Conditions of data sharing mechanism must not be discriminatory between registrants
 - ☞ Independent from size, contribution, time of joining the submission (registration deadlines)
 - ☞ The size of the member must not impact the voice and ability to contribute to the SIEF activities. LR should pay similar attention to all members. For example, SME companies are not to be left out of the communication loop regarding important decisions that impact the cost for a LoA.
 - ☞ Principles in the data sharing agreement independent from deadline
- ✓ Subsequent registrants only required to share according to their own requirements
 - ☞ Joint data package covering >1 substances, vs. 1 specific substance
- ⊘ Do not retain any information up to a date that best suit you

Extra tip – record all steps of the negotiations

ECHA Decision:

- Based on the assessment of documentary evidence which need to demonstrate the efforts made by all the parties
- Establish whether the parties have made every effort on agreeing on the sharing of information and/or its costs in a fair, transparent and non-discriminatory way
- ✓ Record every email / letter exchange, agreed minutes of phone conversations/ meetings / any other contact with the other party
- ✓ If there is no reply, find alternative ways
- ⊘ Do not use an argument with ECHA which was not recorded

 Data sharing disagreement shall be solved exclusively by ECHA dispute procedures

Take home messages

1. Data sharing is compulsory under REACH (multiple registrants of the same substance)
2. Sharing data is sharing the responsibility of success
3. Sharing data requires transparency:
 - ✓ What is to be shared (requirements, deadline)
 - ✓ What is available (LoA, token, costs,...)
4. Data sharing dispute procedures must only be initiated as a last resort.
5. ECHA encourages all parties to continue making every effort to reach an agreement (even if data sharing dispute is submitted)

Thank You!

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