

November 2017

Templates for negotiations on data sharing and joint submission

Background

This document is part of ECHA's efforts to give companies, namely small and medium-sized enterprises (SMEs), practical help to fulfil their obligations under the REACH Regulation.

Companies have repeatedly identified data sharing and joint submission as a challenging and complex task. They are burdensome especially for those SMEs that do not primarily operate in the chemicals sector and that have limited regulatory experience.

The following letter templates are to be seen in this context. They are not intended to be mandatory or prescriptive. They should rather serve as a guideline to make sure that all parties address a range of aspects when entering into data-sharing or joint submission negotiations. Companies affected can themselves assess the appropriateness of the templates on a case-by-case basis and decide which elements they wish to adopt (and at what level). Use of these templates does not prejudice the outcome of a dispute under Article 27 or Article 30 REACH.

Companies/persons are to use the templates at their own risk. The European Chemicals Agency will not accept any liability or warranties resulting from the use of these templates and their application.

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1. Letter template to initiate negotiations on data-sharing or access to the joint submission

Dear Madam, Sir,

We [company name] intend to register the substance [substance name; EC / CAS no.].

To fulfil the data sharing and joint submission obligations, we would like to receive the following information for this substance:

- Price / conditions for a letter of access for all required studies in the tonnage band [1-10 / 10-100] tpa [delete if not needed]
- Price / conditions for the token to access the joint submission (as an opt-out registrant), without any access to the jointly submitted data [delete if not needed]
- Price / conditions for access to the studies / endpoints listed below:
 - o Study A
 - o Study B
 - o ...[delete if not needed]

In this respect, could you please also provide an itemisation of all incurred costs, in line with the requirements of the Commission Implementing Regulation on joint submission of data and data sharing? More specifically, we would like to ask you for an itemisation including the following information:¹

- Costs related to data: any costs required to perform a study, acquire access (co-ownership, possession or right to refer) to data owned by third parties, contract laboratories, monitoring performances or fulfil an information requirement with an alternative method.
- Costs related to administrative work: any costs for creating and managing the SIEF and the data-sharing agreement as well as managing the joint submission.

We would further like to inform you that we do not have any data available / hold the following studies on the substance. [include additional information on studies, e.g. year, reliability, costs, etc.]

Could you please provide an answer by [15WD]?

For further questions, please contact us via [email / phone no]

Kind regards,

¹ Compare 'Guidance on data-sharing' for details, namely annex 3 'Cost itemisation'

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2. Letter template: reminder

Dear Madam, Sir,

With regard to our email dated **XX/YY/ZZZZ**, we would like to remind you that we have not yet received an answer from your side.

Could you please provide an answer by [**10WD**]?

Kind regards,

3. Further advice

To help you in your negotiations, ECHA has prepared practical advice and support documents. They are available in your language and can guide you through your negotiations.

- REACH 2018 (see especially phase 3 'Get organised with your co-registrants'):
<https://echa.europa.eu/reach-2018>
- Practical advice for sharing data and submitting jointly with co-registrants:
<https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations>
- Typical costs elements in data sharing:
https://echa.europa.eu/documents/10162/13631/factsheet_costs_datasharing_en.pdf/c4595798-0634-4f3b-a247-d518b999ba1f
- Practical examples – REACH registration (see '3 Get organised with you co-registrants'):
<https://echa.europa.eu/support/registration/practical-examples>
- Joint submission:
<https://echa.europa.eu/regulations/reach/registration/data-sharing/joint-submission-of-data>

If you have further questions or your negotiations have come to a standstill, you can also contact ECHA for further advice before potentially filing a dispute claim in accordance with Article 27 or Article 30 REACH.

To contact ECHA, please visit: <https://echa.europa.eu/contact>