ECHA
EUROPEAN CHEMICALS AGENCY

In brief

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Typical cost elements in data sharing

The key principle of cooperation for data sharing is to make every effort to reach an agreement on how to share data and its costs. This needs to be done in a fair, transparent and non-discriminatory way.

BACKGROUND

REACH requires companies registering the same substance to share data to avoid unnecessary testing on animals, and to reduce costs. This is why registrants have to work together to find an agreement on how to share the information and its costs, and to form a joint submission.

Data sharing is not designed to generate profit for the data owner, but only to share the actual costs between all co-registrants (you, other potential registrants and existing registrants) who need to register the substance.

Similarly, the obligation to submit jointly is not designed to generate profit for the lead registrant, but to share costs that relate to the creation and administration of the joint submission. However, it can be reasonably expected that these costs are rather low.

This document gives an overview of the potential cost elements of data sharing.

GENERAL PRINCIPLES

You and your (potential) co-registrants need to make every effort to reach a fair, transparent and non-discriminatory agreement. This is regardless of whether you share data or seek access to the joint submission.

Cost breakdown

You have the right to receive a cost breakdown ('itemisation') that lists and justifies all costs, so that you are able to determine to which extent they relate to your information requirements.

Example of a cost breakdown

Cost item	Relevant tonnage band	Study cost if applicable	Admin. costs	Justification
Study 1	1-10 t/y	€ 1 000	€ 70	Justification 1
Study 2	1-10 t/y	€ 2 000	€ 60	Justification 2
Study 3	1-100 t/y	€ 3 000	€ 130	Justification 3
Token	n/a	n/a	€ 150	Justification 4
SIEF commu-nication	1-10 t/y	n/a	€ 1 000	Justification 5
Etc.	...	...	...	...

Future costs

Costs may also arise in the future. There could be new data available that you want to include in the joint dossier, or you may be asked for data following substance evaluation. While you might not know the actual sums involved, you still have to agree on a mechanism that allows you to share these costs in a fair, transparent and non-discriminatory way.

DATA AND ADMINISTRATIVE COSTS

The costs of registration normally consist of data and administrative costs. While it is not always possible to precisely divide between data and administrative costs, this document gives advice on the distinction. Annex III to the *Guidance on data sharing* also gives examples of data and administrative costs.

Data costs

Each individual data item comes with a price (endpoint-by-endpoint). This price can include the costs for performing a test, for buying access to required data or fulfilling the information requirement with a non-testing method. The basis for the calculation of data costs is the actual cost of performing a test or conducting scientific work to fulfil an information requirement for REACH registration.

Study costs can be determined using either of the following methods:

» **Historical costs**: the actual costs to perform the test usually with an invoice from the laboratory. Conducting expert work to fulfil an information requirement usually also comes with an invoice; or

» **Replacement costs**: estimated costs for performing a study that can be used, for example, when there are no invoices for a study, when a study has been performed in-house or when the scope of an existing study goes beyond the regulatory requirements.

Both approaches are equally valid; you are free to agree on the appropriate basis for your cost calculation.

Administrative costs

There are two types of administrative costs:

1. Costs related to data

Parts of the administrative costs are data-specific. For example, costs to conduct a literature search or to develop the reasoning for a data waiver relate to an endpoint and not to the entire dossier. Another example is the administrative costs for dealing with a laboratory to perform a test.

2. General administrative costs

Parts of the administrative costs are not specific to an information requirement. For example, the costs related to managing the substance information exchange forum (SIEF) or the joint submission, or for communication within the SIEF apply to all members equally.

REACH allows data sharing for individual studies: you only need to pay for costs relating to the data you need. This also means that if you negotiate access to individual studies, you only need to pay your share of the general administrative costs.

CALCULATION METHODS AND COST FACTORS

Reimbursement scheme
Your individual proportion of the costs depends on how many co-registrants share the data. It makes a significant difference if the costs are shared between 2 or 200 registrants.

A reimbursement scheme is mandatory and will make sure that the costs are equally shared. Each time a new potential registrant buys access to the data, the overall costs for each co-registrant will reduce. When and how frequently the price is re-calculated needs to be agreed. You can check the current number of co-registrants on ECHA's website (and once you register you can monitor it in REACH-IT).

As different data-sharing requests will cover different endpoints, an objective reimbursement mechanism will need to take into account many different situations.

You may also decide unanimously not to have a refund mechanism but instead agree to decrease the compensation to the data owner upfront – with the expectation that more registrants will be sharing the cost. But, bear in mind, that any newcomer has the right to request a reimbursement mechanism. If you decide to waive the reimbursement mechanism, make sure you have good arguments to also convince potential newcomers.

Access to data or right to use data
Different rights on the use of data can be agreed between registrants. These include, for example:

» the right to refer to the data for registration purposes, for example, with a letter of access (LoA);

» the right to use the information for other purposes than REACH and also outside the EU;

» co-ownership of the data.

Interest and risk premium
You may be asked by the data owner to pay interest or a risk premium.

A risk premium covers the risks taken and investments made by the data owner, for example, for performing a test with an uncertain outcome.

Data owners need to justify why their demands are fair, transparent and non-discriminatory. There is no situation that explicitly requires the application of interests or a risk premium.

You may challenge the collection of interest or a risk premium as such, as well as the rate applied by the data owner.

REACH does not require you to cover the financial implications of requirements related to previous registration deadlines which were not applicable to you. You have the right to ask for objective criteria justifying the interest rate or the risk premium.

Annual price increases
Make sure that you are not requested to pay for an increase of the price just because you register later than your co-registrants. Such increases - sometimes called 'latecomer's penalties' or 'early bird incentives' - are not allowed.

Inflation
You may be asked by the data owner to pay inflation to individual cost items or an average inflation to the overall costs, especially when significant time has passed since the costs were incurred.

However, there is no situation that explicitly requires the application of inflation. Data owners need to justify why their demands are fair, transparent and non-discriminatory.

You may challenge both the collection as well as the rate of inflation applied by the data owner.

Example: You want to use older data (from the 1980s or 1990s) that has already been compensated for in the past under different regulatory regimes. If you are asked to compensate inflation, you could well argue that any costs have already been paid off.

Additional costs
You can also consider negotiating on any of the following, keeping in mind that neither you nor your co-registrant is obligated to buy or sell any of these:

» **Chemical safety report (CSR)**: For registrations above 10 tonnes a year, you need to submit a CSR. You can buy it from your co-registrant if it covers your uses, or prepare it yourself. If you decide to prepare your own CSR, you should not pay any costs related to the preparation of your co-registrant's CSR. For registrations between 1-10 tonnes a year, a CSR is not required.

» **Guidance on safe use of the substance:** As the chemical safety report is not needed for registrations between 1–10 tonnes a year, you will need to submit more information in the *guidance on safe use* section of your registration dossier. The *guidance on safe use* needs to be consistent with the safety data sheets you supply to your customers. You may consider sharing the costs of preparing the guidance on safe use jointly with your co-registrants.

FURTHER INFORMATION:

Practical advice for data-sharing negotiations
http://echa.europa.eu/regulations/reach/substance-registration/data-sharing/practical-advice-for-data-sharing-negotiations

Joint submission
https://echa.europa.eu/regulations/reach/registration/data-sharing/joint-submission-of-data

Data sharing
http://echa.europa.eu/regulations/reach/substance-registration/data-sharing

Guidance on data sharing
http://echa.europa.eu/guidance-documents/guidance-on-reach?panel=datasharing#datasharing

Data-sharing dispute decisions
https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach

Practical Guides on the Biocidal Products Regulation – Special Series on Data Sharing - Data Sharing
http://echa.europa.eu/practical-guides/bpr-practical-guides

Decisions of ECHA's Board of Appeal
http://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions

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