

Rules on the costs sharing for AIFe REACH registration dossiers

Costs of the AIFe REACH registration dossiers are based on three parts:

1. Study costs
2. Administrative costs
3. CSR costs (if applicable)

1. Costs of the studies for the actual endpoints

The quality of the reports is proposed in accordance with the Klimisch et al.¹ method by classifying the report into one of the following categories:

- 1) reliable without restriction
- 2) reliable with restrictions
- 3) not reliable
- 4) not assignable.

The replacement cost for the key study for each endpoint has been adopted depending upon the Klimisch rating assigned to the study. The replacement values are based on VCI costs study of 2007. The actual value has been used for jointly developed by the consortium/HPV/Incopa sector group, or purchased studies.

Correction factors will be used to transparently increase the actual replacement value per end point. The correction factor will be based on the final replacement value agreed.

More than one correction factor can be applicable for a certain study value.

- a) Plus 20% Risk premium for studies listed in Annex VII - X of the REACH regulation.
- b) A surcharge to the sum total of experimental costs (substance testing and analysis) is charged for administrative expenses (processing, monitoring and professional support by the commissioning party, travel expenses, archival of the test substance and raw data). The surcharge depends on the experimental value of the study (table 1).
- c) Robust summaries contributed by the supplier or developed by experts commissioned by the Technical Committee should be compensated by 30% of the value of the admin costs according to the table 1.

Table 1. Surcharge to the total study value of administrative expenses.

Study value (€)	Correction factor	
	Administration (€)	Administration (%)
3000	750	25 %
5000	1000	20 %
20000	3000	15 %
50000	5000	10 %
100000	7000	7 %
200000	10000	5 %
300000	12600	4.2 %

Deduction factors may be used to transparently reduce the actual replacement value per end point. The deduction factor will be based on the final replacement value agreed upon.

More than one deduction factor can be applicable for a certain study value:

- a) Minus 20% for a Klimisch 2 study;

¹ Klimisch/Andrae/Tillmann, *A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data*, Regulatory Toxicology and Pharmacology 25 (1997), pp. 1–5.

- b) Minus 100% for a Klimisch 3 or 4 study. However, on a case by case situation, the consortium can suggest to include Klimisch 3 & 4 studies if they significantly contributed in the filling of a data gap (e.g. by weighted evidence). The deduction factor must be determined on a case by case basis;
- c) Minus 50% for just a letter of Access for REACH usages by a SIEF Member (no transfer of the actual study report or study data).

If data are to be used for another purpose, a bilateral agreement is developed with the data owner.

2. Administrative dossier costs

Expenses for Registration dossier preparation: Pre-consortium, Consortium secretariat, financial management, dossier preparation costs, lead registrant costs. The Administrative Costs have been shared to each sub category in the consortium.

3. CSR costs (if applicable)

Expenses for Registration dossier preparation: CSR costs (technical service provider).

4. Cost Sharing basis

Cost calculation is based on Cefic's option 1:

- Calculation of costs before each deadline and possible reimbursement in 2013 to 2010 registrants and in 2018 to 2010/2013 registrants and threshold for reimbursement (1000 €).

The cost sharing is based on:

- Study costs:
 - Sharing based on study/data needs
- Administrative costs and CSA/CSR costs (who need a CSR/CSR):

For companies needing data for a lower tonnage band than the "> 1000 Tons" for a salt category, the following multiplicative factors apply to the administrative costs related to the category (the figure to be considered is the highest manufacturing / importing tonnage band) :

Volume Range	Multiplicative factor
>1000	1.0
100 - 1000	0.7
10 – 100	0.4
1 – 10 and intermediates	0.1

Access to a full dossier for a certain tonnage band: any potential Registrant can get a letter of access and electronic data to be entitled for the usage of the full Registration dossier for its Registration under REACH after fulfilling its cost compensation requirements agreed upon.

The costs of the studies, test data and information required as well as the costs for new studies required are equally shared between the joint registrants.

Access to individual data: Any SIEF Member (including for read across purposes) can get a letter of access to be entitled for the usage agreed (by default this access is restricted to REACH Registration only) after fulfilling its cost compensation requirements agreed upon.

The costs of the studies are calculated by endpoint so that a cost allocation mechanism by endpoint is available for the companies which use their own studies.