Rules on the costs sharing for AlFe REACH registration dossiers

The AlFe REACH Consortium has registered substance falling under three groups:

a) Aluminium salts (4 registrations)
b) Iron salts (5 registrations)
c) Sodium Aluminate (3 registrations)

The dossiers of each group of substances have been prepared on the basis of a category approach. The work done on each dossier is relevant for the others of the same group and read across is extensive. For this reason, costs are shared by category of substances. A LoA buyer purchasing a Letter of Access for a category can register all the substance falling under that category.

Costs of the AlFe 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 studies jointly developed by the Consortium/HPV/Incopa sector group, or purchased from other data owners.

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

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.

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

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

	Correction factor	
Study value (€)	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;

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 a letter of Access giving the right to refer to the joint registration dossiers and to the data contained therein only for the purpose of a registration under EU REACH by a co-registrant (no transfer of the actual study report or study data and no co-ownership on the dossier or on the data granted).

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

2. **Administrative dossier costs**

The expenses for the preparation and maintenance of the registration dossier and of the joint submission include *inter alia*: pre-consortium costs, Consortium secretariat, financial management, dossier preparation costs, Lead Registrant costs, fees of consultants.

These costs have been shared to each sub category in the Consortium. The allocation of administrative costs makes use of multiplicative factors to take into account the estimated workload linked to each tonnage band (see section 4 below).

3. **CSR costs (if applicable)**

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

costs specifically related to the CSR, if any

4. Cost Sharing basis

Costs are re-calculated after each deadline. The registrants may then either be reimbursed (threshold: 1000€) or invoiced."

4.1 Study costs (data costs)

Study costs are shared equally among the registrants, according to the rules outlined in paragraph 1 above, and taking into account the information requirements of each registrant. For the sharing of cost of studies generated following a final decision of ECHA, see paragraph 5 below.

4.2 Administrative (non-data) costs

Administrative costs and CSA/CSR costs (who need a CSR/CSR) are shared on the basis of multiplicative factors.

Since a co-registrant who purchased a Letter of Access for a category can register all the substance falling under that category, such co-registrant will need to contribute financially to non-data costs related to highest tonnage band he registered within the relevant category. The table below shows the allocation of administrative costs to the different tonnage bands.

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

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.

Access to individual data: Any co-registrant (including those seeking access 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.

5. Post registration cost-sharing obligations

5.1 Administrative (non data) costs

Registrants are bound to fairly contribute to additional administrative costs (either already incurred into by the Consortium or only estimated) after the purchase of a Letter of Access. A provision for future administrative costs may be included in the price of the Letter of Access. . The amount of such provision may also depend on the estimation of the workload on the Substances that is reasonably foreseen for the following years.

These costs will be shared according to the standard rules for sharing administrative costs outlined under paragraph 4.2 above.

5.2 Study (data) costs

5.2.1 Voluntary updates

Study costs following voluntary dossier updates will be shared according to paragraph 4.1 above.

5.2.2 Cost sharing following a substance evaluation decision

The evaluation of the registration dossier by ECHA (compliance check or the assessment of a testing proposal) or of the substance by a Member State competent authority may trigger new requirements (e.g. generation of new data) which would need to be addressed among registrants, and may lead to a request to submit further information. As a result, agreement on generating and sharing data and costs will be needed and will lead to an update of the joint submission. Hence data-sharing does not only apply to "existing" studies but also to studies which will be needed for ensuring that the registration is and remains compliant with REACH. According to the Implementing Regulation (EU) 2016/9 (Article 4(2)) co-registrants shall consider in their cost-sharing model a mechanism for sharing the costs resulting from a substance evaluation decision. Pursuant to that Regulation, they are also required to consider the possibility to cover costs of future additional information requirements for that substance other than those resulting from a potential substance evaluation decision (e.g. potential dossier evaluation decision):

a) Data costs that can be linked to standard REACH endpoint will be calculated according to the rules set out under paragraph 1 above and shared among registrants based on their tonnage band requirements.

b) Data costs requested by a final decision on Substance Evaluation, according to Title VI REACH, will be shared according to the rules set out in paragraph 1 with the additional application of the multiplicative factors listed below, in order to take into account the different level of investment of the registrants in the different tonnage bands:

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

c) Data costs following a final decision of the Competent Authorities and not falling under the cases described paragraph 5.2.2 a) or 5.2.2 b) will be shared according to the same rules applicable under paragraph 5.2.2 b).