

Note on the need for a fair cost sharing in SIEFs

7th September 2010

Cefic reminds its members about the importance of having a fair, transparent and non-discriminatory cost sharing system in SIEFs. Failure to do so may entail a breach of the REACH Regulation and/or competition law and be subject to enforcement actions.

Articles 27(3) and 30 (1) of REACH include the obligation to make every effort to share costs in fair, transparent and non discriminatory way; in this context, Cefic would like to remind the following principles of cost sharing:

- **Cost sharing compensation should reflect the work done by the consortium or lead company (ies)** in the preparation of the dossier, the actual cost of the studies as well as the administrative work for the SIEF communication, etc.
- **Cost should be charged only for necessary data**, so that SIEF members are not required to pay for what they do not require e.g. higher tonnage bands, other purposes than REACH, etc.
- If a **SIEF member** already has data for a certain end point, he **should not have to pay the Lead Registrant/consortium for that again**.
- Cost sharing methodology should be always **objectively justified and documented**.
- **“Fair, reasonable and non discriminatory” requirement should apply to all studies** (not only animal studies) and to ‘non-study’ costs such as administrative expenses, dossier preparation costs, etc. This general principle is also applicable for competition law compliance.
- **Overhead costs** must be reasonable
- **Assessment of fairness** of cost sharing proposed by the Lead Registrant/consortium should be **based on a case by case analysis** (e.g. costs, number of SIEF members per deadline). There is no standard fair cost sharing.
- **Different treatment among SIEF members must be strictly limited** to situations that are **objectively** different (eg. different scope of granted rights) and must always be **justifiable**.
- **The addition of detailed information on costs sharing criteria** in the SIEF agreement is not strictly required but highly **recommended**.
Such detailed information may include studies valuation rules, cost sharing principles, additional factors (administrative cost, risk premium) and deduction factors (e.g. discount for REACH purposes only). A mechanism for reimbursement/additional payment may be envisaged in some cases and may include a threshold. The cost sharing principles that are applied must be explained somehow to all SIEF members.

See also:

Cefic note on the need for a transparent communication on cost sharing in SIEFs:
http://cefic.org/Files/Publications/Cefic-note_transparency-on-cost-sharing-in-SIEFs_310510.pdf

Cefic REACH competition law guidance:
http://cefic.org/Files/Publications/competition_law_compliance_guidance.pdf

Cefic recommendation on Letter of Access:
http://cefic.org/Files/Publications/Cefic_recommendation_letter_of_access_FINAL.pdf

For further information:

ECHA guidance on Data sharing: http://echa.europa.eu/datasharing_en.asp

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