

LEGAL NOTE - REACH: FAIR AND TRANSPARENT COST SHARING IN SIEFs

05 December 2013 (first edition)

Cefic points up 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.

I. PRINCIPLES

a) Fairness:

Data and their costs need to be shared in a fair manner. Cefic would like to remind the following principles of fair cost sharing:

- SIEF members **cannot be forced** to pay for data and information they do not require.
- Prices should be **differentiated per tonnage bands** and per type of registration (e.g. dossier for intermediate uses). Under normal circumstances, to apply indistinctively the same compensation (flat fee) for access to the 4 types of dossier based on tonnage bands (above 1000 T, 100-1000 T, 10-100 T and 1-10 T) is unfair.
- The differentiation per tonnage band and per level of information requirements is mainly applicable to **study costs** (not only vertebrate animal studies). The way to distribute the '**non-study**' costs such as administrative expenses, dossier preparation costs may follow a different approach via an equal division between all the co-registrants, regardless of their tonnage band.
- If a **SIEF member** already has valid data for a certain end point, he **should not have to pay the Lead Registrant/consortium for that data again**.
- Cost sharing methodology should always be **objectively justifiable**.
- **Overhead costs** must be reasonable.
- **Assessment of fairness** of cost sharing should be **based on a case by case analysis** (e.g. costs, number and type of studies to be newly generated, estimated number of co-registrants). There is no single standard fair cost sharing method and the comparison between the prices of the Letter of Access (LoA) between 2 substances is meaningless when all the specific factors of each substance are not assessed at the same time.
- **Different treatment among SIEF members must be strictly limited** to situations that are **objectively** different and must always be **justifiable**.



- The same cost sharing mechanisms should be applied **regardless the different times a co-registrant may join** the joint submission: the principles established by the 2010 registration deadline should apply identically for the 2013 & 2018 registration deadlines.
- **Different scope of granted rights** may be considered (e.g. co-ownership on studies vs. simple right to refer; right to use for REACH purposes only vs. for any regulatory purposes; right to use the data for read-across purpose at no additional cost vs. obligation to pay an additional compensation for each substance the same data is used for). If such is the case, it should trigger different respective prices of the LoA: co-registrants should pay a compensation for access to the joint dossier or to data always dependant on the rights they get on it.
- The establishment of a **reimbursement scheme** based on the actual number of co-registrants may ensure equal sharing of the costs. This means that when the number of SIEF members that have actually be granted an access to the joint dossier is higher (or lower) than the estimation initially used to calculate the amount of the shares, the cost per member will decrease (or increase) and partial reimbursement (or additional invoicing) may take place.
However, the exclusion of the possibility of reimbursement or additional payment does not preclude the cost allocations to be fair and transparent.
- Various elements could be taken into account in the **data valuation** and more than one system exists. As an example of these, replacement costs could be taken into consideration. These are i.e. the price that could be paid today to obtain the same data could be a method of evaluation except where the data owner can show that the actual “historic costs” are higher.
- **Data value correcting factors** may also be taken into consideration: the parties could agree on correcting factors that may either increase or decrease the study value for cost sharing purposes. Typical examples of factors **increasing** the study value could be: interest/inflation (when historic costs are used as baseline), administrative, archiving expenses and other dossier preparation costs. Typical examples of factors **decreasing** the study value could include possible study deficiencies compared to the agreed protocol.
- **Risk premium** could also be considered: in certain circumstances, the decision to conduct a study has involved a risk for the initiator according to which the project may not be successful in generating the information desired (with no possibility for reimbursement). Accordingly, an uncertainty premium may be assigned to the study.
- The final price of the shared data **cannot be the outcome of the haggling** between the interested parties. The costs of the data to be shared must be the same for all registrants with the same data requirements and must reflect the value of that data.

b) Transparency:

Cefic would like to remind the following principles of transparent cost sharing:

- The cost sharing principles that are applied must be **explained in a clear and transparent way** to **all** (potential) SIEF members.
- It is recommended that the options for data and cost sharing are explained to the SIEF members **at an early stage**.

- The provision of the information on costs sharing should **never be conditioned by the Lead Registrant to the payment of a specific fee or provision**: access to the details of the cost sharing and the methodology should be free.
- Cost sharing compensation should reflect the work done by the consortium or lead company(ies) in the **preparation of the dossier** (e.g. redaction of the study summaries, preparation of the IUCLID file, contribution to the preparation of the project in the form of effort – usually called sweat equity), as well as the **administrative work** for the consortium and the SIEF management). Therefore detailed information on those factors and the corresponding costs should be provided to the SIEF members.
- It must be ensured that cost sharing criteria are carefully explained using a coherent and objectively justified **methodology that is well documented**.
- Such detailed information on the cost sharing **methodology** may include studies valuation rules, cost sharing principles, additional factors (administrative cost, risk premium) and reduction factors (e.g. discount applied for access rights limited to REACH purposes only, compared with access rights for any regulatory purposes).
- The fact that a **mechanism for reimbursement/additional payment** (which may include a certain threshold) has been foreseen should be mentioned.
- The fact that possible future **costs (e.g. related to the Evaluation process** (Dossier Evaluation and/or Substance Evaluation), costs related to future updates of the joint dossier, sweat equity and administrative costs for maintaining the dossier) have either already been foreseen or will have still to be shared in due time should be indicated.
- It should be clearly described whether the **sections of the dossier not subject to mandatory joint submission** (e.g. Chemical Safety Report) are covered by the joint dossier and by the price of the LoA.
- Detailed information on cost sharing may include a **breakdown of the costs** of the studies covered by the LoA, their respective **value** or the number of **expected registrants**.
- The **content of the documents that will be provided** to the co-registrant by the Lead registrant/consortium upon reception of the payment of the LoA should be described. It is not advised that SIEF members only receive the token following the payment of the relevant compensation to be part of a Joint Submission. As a minimum, SIEF members should have access to the information submitted by the Lead Registrant on behalf of the Joint Submission SIEF members (article 11(1) paragraph 2) ideally via the reception of the IUCLID in a i5z-file. This means that by paying a LoA in order to participate to the Joint Submission, the SIEF members should have access to the endpoint results for which they have paid for as well as a copy of the robust study summaries, and study summaries if available, unless flagged as confidential. Where companies will financially contribute to e.g. the Chemical Safety Report, they should also receive this information. This should be clearly described in the communication regarding the access to the joint dossier and the corresponding compensation.
- Lead Registrants and consortia should explain the details of cost sharing principles to potential registrants in the SIEF, either via a **progress report** in the IT platform used in the SIEF, a **newsletter** or a **simple communication** by email.
- The inclusion of details on **cost sharing criteria in contractual arrangements** agreed in the SIEF (e.g. via the Annexes of the Cefic model SIEF agreement) can also be useful in view of a better transparency regarding the way the costs will be shared among the SIEF members.

- When some data in the joint dossier are not covered in the scope of access rights granted to the co-registrant via the LoA, the Lead registrant should clearly indicate that the **co-registrant still has to individually acquire rights** on such data from third parties. Such situation where the data and license package provided by the LR does not cover all the registration needs of the co-registrants occurs when some data are owned by third parties that have not granted to the LR the right to sub-license their studies to the co-registrants.
- If requested to the Lead Registrant, the scientific justification on the approach followed in the **selection of data** should be provided.
- In case a co-registrant intends to **opt-out** for certain information (art. 11.3 REACH), he may **first communicate with** the Lead Registrant, as part of the efforts to be made in order to reach an agreement. In that case, reasonable time to react should be given to the Lead Registrant before taking any further step to an opt-out.
- Since a registrant that opts out is still part of the joint submission, the Lead Registrant should still provide him the **REACH-IT token** in order he can confirm membership to the joint submission.
- When a registrant opts out of all the shared data, being still formally a member of the joint submission and in need of the REACH-IT token, he may still be asked to **compensate** a fair share of reasonable **non-study costs** incurred by the Lead Registrant or consortium, such as managing the SIEF.
- When a company has initially registered individually out of the joint submission (e.g. at the beginning of the SIEF process when the Lead registrant was not identified) and now would like to enter in the joint submission, that **individual registrant** should contact the corresponding Lead Registrant in order to learn about the conditions. In most of the cases, this may imply the subsequent payment of the relevant compensation. When that registrant possesses already its own set of data (see point above), he may still be asked to compensate a fair share of reasonable non-study costs.

II) RECOMMENDATIONS TO CO-REGISTRANTS

During the cost sharing process, potential co-registrants should:

- answer communications addressed by the Lead Registrant;
- initiate the negotiations sufficiently early before the upcoming registration deadline in order to make it possible to reach an agreement;
- record every exchange (e.g. email, letter, meeting);
- ask for clarification of any misunderstanding with precise questions, in case of concern;
- ask the existing registrants which data are covered by the joint submission and what are the costs of this data when they would like to constructively question a proposed price;
- pay attention not to question all decisions taken so far in the SIEF;
- give reasonable time for the Lead Registrant to provide answers;
- express any concern directly to the other party;

- express concerns on each relevant specific point (e.g. quality, cost of dossier, cost of studies) and not as a whole;
- not consider the cost of a letter of access as a question of commercial negotiation, since the costs are divided among the members of the joint submission and all co-registrants have to be treated in the same way;
- propose alternative solutions when negotiations are blocked, remain proactive and open in their communications;
- not stop discussions prematurely.

III) REMEDIES

In case of disagreement on cost and data sharing, the parties may envisage to request the services of a **mediator** (being either a service provider or a law firm for example). The intervention of an independent third party may contribute to an agreement.

In case one party considers that the other party has not made all efforts to reach an agreement, the process of “**SIEF dispute**” can be initiated, with **request to ECHA** to intervene, via a formal claim to be initiated as a last resort. If ECHA considers that the request is founded, i.e. if it is demonstrated by documentary evidence that the other party has not met his obligation to make every effort to share the data and its costs in a fair, transparent and non-discriminatory way, although the potential registrant has made such efforts, then the potential registrant will receive from ECHA the permission to refer to the data,

According to the contractual arrangements in place in the SIEF, the parties may also attempt to settle amicably any disagreement either by **arbitration** or via ordinary **national civil courts**.

At last, when there is some reason to consider that the competition law rules may have been breached, depending on the case, the national or European **competition law authorities** or the competent national courts may be approached.

IV) FOR FURTHER INFORMATION

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

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

This paper has been developed by the Cefic Legal Aspects of REACH Issue Team.

The information contained in this document is intended for guidance only and whilst the information is provided in utmost good faith and has been based on the best information currently available, it is to be relied upon at the user's own risk. No representations or warranties are made with regard to its completeness or accuracy and no liability will be accepted by Cefic nor any company participating in Cefic for damages of any nature whatsoever resulting from the use of or reliance on the information.