DIRECTORS' CONTACT GROUP

DCG3/7/AP3a
1 October 2014

FIRST EDITION
WITH NOTE, JAN 2016

IMPORTANT NOTE:

For most of its content, this DCG recommendation has been superseded by the legally binding Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), published in the Official Journal of the European Union, OJ L 3/41, 6.1.2016.

Readers are advised to consult the text of the Commission Regulation with which companies cooperating in a Substance Identity Exchange Forum (SIEF) need to comply.

The Commission Regulation can be found via the following link: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&from=EN.

The Directors' Contact Group (DCG) may complement the Commission Implementing Regulation by a more limited set of recommendations, in due course. In their absence, this recommendation is to be regarded as obsolete.

DCG Secretariat, January 2016

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FAIR, TRANSPARENT AND NON-DISCRIMINATORY COST SHARING IN SIEFS

The Directors' Contact Group (DCG) emphasises the importance of having a fair, transparent and non-discriminatory cost sharing system in SIEFs[1]. Failure to do so may entail a breach of the REACH Regulation and/or competition law and be subject to enforcement actions.

[1] Several types of costs need to be distinguished: 1) Costs related to **SIEF administration** (e.g., setting up communication channels for the SIEF, managing the financial aspects of the SIEF and managing the joining of new members to the SIEF); 2) **costs of the tests** needed, and 3) costs for **managing** the performance of **such tests** (procuring a suitable test laboratory and monitoring the progress of their work). In addition, costs related to **joint submission**, such as 4) managing the joint submission (e.g. creating the joint submission in REACH-IT and communicating it to member registrants), and actual 5) dossier preparation, maintenance and update costs (e.g., making relevant literature searches, and input all the information in a IUCLID dossier) will be incurred. Of these, 1, 3, 4 can also be called "administrative costs".

I PRINCIPLES

a) Fairness:

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

1. SIEF members **cannot be forced** to pay for data and information they do not require.
2. If a **SIEF member** already has valid data for a certain endpoint, the member **should not have to pay the lead registrant/consortium for that data again**. For this reason, any such SIEF member should inform the other members of the SIEF of the possession of such valid data well in advance, ideally at the start of the dossier preparation, and may have to share this information with the other SIEF members.
3. Providing information for establishing **substance sameness** is a prerequisite for determining whether a company is a member of a certain SIEF or not. Therefore, compiling such information should not be subject to any cost compensation among the concerned parties.
4. **Assessing 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. Comparing between the prices of the Letters of Access (LoA) charged for two different substances is only sound when all the specific factors of each substance are assessed simultaneously.
5. The members of the SIEF may have agreed that in case of a **surplus** (e.g. due to more members joining the SIEF than anticipated), the additional revenue will serve to cover future joint expenses such as possible further obligations that can be anticipated in case of dossier/substance evaluation.

   A final settlement can be foreseen after the 2018 registration deadline, or later if agreed. Therefore the absence of an immediate reimbursement scheme in case of a surplus does not necessarily render the cost allocation unfair.
6. **Administrative costs** of a reimbursement scheme may become uneconomic. In such a case all parties which would be entitled for a reimbursement can agree to use this income otherwise, and this can be reflected in the SIEF agreement.
7. Co-registrants who have contributed their fair share to the initial registration dossier costs should contribute to **costs incurred for updating** the dossier according to analogous, or at least similar, sharing principles.
8. Due to the different information requirements based on the volume band of registration, 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 four types of dossier based on tonnage bands (above 1000 tpa, 100-1000 tpa, 100-1000 tpa and 1-10 tpa) is deemed unfair.
9. The differentiation per tonnage band and per level of information requirements is mainly applicable to **study costs** (not only vertebrate animal studies) and to the administrative costs related to obtaining the studies.

10. In principle, the SIEF management costs should also be shared proportionally. This is particularly relevant whenever the **'non-study' costs** can be assigned to the workload exclusively in the context of 2010 or 2013 registration deadlines. (For example, registrants for 2018 shall not be asked to pay for meetings on testing proposals, on selection of data for higher tonnage bands, cost of invoicing and reimbursing of 2010 or 2013 registrants before 2018, discussions on CSR (not mandatory for 1-10t), negotiations on data sharing with 2010 and 2013 registrants, etc.). The way to distribute the remaining 'non-study' costs, whenever these are neutral and cannot be linked to some specific studies, such as SIEF general management and administrative expenses, and provided these costs are reasonable and not disproportionate, may follow a different approach, e.g., via an equal division between all the co-registrants, regardless of their tonnage band.

11. The costs can also be differentiated according to the **scope of rights granted** by each LoA, e.g. co-ownership of 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 for which the same data is used. Various elements can be taken into account in attaching value to the data; and more than one system can be applied. One example of these methods of valuation is to consider replacement costs: what would be the price to be paid today to obtain the same data (e.g. use of the Fleischer list or other similar list). This is the most common approach. Another way to determine the value of a study in view of sharing its cost is to refer to the costs at the time of its generation as long as these can be demonstrated in a proper and transparent way.

12. Registrants need to be made aware that (**robust) study summaries** of studies used for notification under Directive 67/548/EEC (NONS) that were submitted[2] **more than 12 years previously** can be used for free for REACH Registration purposes and are exempt from compensation. No compensation for this information should therefore be asked from the other SIEF members.

13. **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: inflation (when historical costs are used as the 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. No cost shall be associated with data submitted more than 12 years ago.

14. Where appropriate, a **risk premium** could also be considered: in certain circumstances, the decision to conduct a study involved a risk for the initiator; 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. However, this has to be well documented and transparently justified.

15. When a registrant opts out of all the shared data, being still a member of the joint submission, the respective registrant may still be asked to **bear** a fair share of reasonable SIEF administration **costs for the joint submission**.

16. In case of **partial opt-out**, a registrant can be requested to pay for accessing that part of the jointly submitted data from which the respective registrant did not opt out.

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[2] Date of submission for the purposes of notification is not equal to the date of performance of the study.

b) ***Transparency:***

The DCG would like to recall the following principles of transparent cost sharing:

17. **Access to the details** of the cost sharing and the methodology behind it for a given SIEF must be free and made available in a reasonable time to the members of that SIEF in accordance with the principles further described in this note, and in particular under points 19 and 22.

18. 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** should include study 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).

19. The cost sharing principles that are applied in an **existing** and already working **SIEF** must be explained in a clear and transparent way to all SIEF members. To avoid disputes it is recommended that this is undertaken at an early stage and is described preferably in the SIEF agreement (see e.g. Annex 3 of the Cefic model SIEF agreement). This effort must be repeated when requested by a subsequent potential registrant.

20. In a SIEF which becomes active for the first time it is recommended that the options for data and cost sharing are developed by the SIEF members at an early stage and described preferably in the **SIEF agreement**. In that respect it can be useful to apply or adopt cost-sharing mechanisms from other already working SIEF which have proven to be fair and functional.

21. **Administrative costs** must be reasonable and their basis well recorded and time tracked. On request a copy of the relevant book-keeping and time tracking must be made available to any active SIEF-member with tangible intentions to register (which can be demonstrated e.g. by signing the non-disclosure agreement), except in cases where reasonable default assumptions are made and agreed. An **audit clause** may also be foreseen in the SIEF agreement, particularly for large SIEFs.

22. Cost sharing compensation should reflect the work done by the active SIEF members 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 SIEF management, and **separate between the two**. Detailed information on those factors and the corresponding costs should be provided to the SIEF members.

23. The SIEF agreement should also address **possible future costs** triggered by ECHA's processes or other update needs (be it a reserve fund established upfront or money collected on a needs basis). For example, registered substances are subject to dossier and substance evaluation, which may lead to requests for further information on the substance covered by the SIEF, necessitating also registrants for the 2018 deadline potentially to consider additional data for their own registrations (however depending on the information requirements related to their tonnage bands). In particular, circumstances where approximate costs can already be estimated (e.g. pending testing proposal) should be communicated to the registrants expected to contribute to these costs.

24. The fact that a **mechanism** for reimbursement/additional payment (which may include a certain threshold) has been foreseen should be **clearly communicated** (e.g. in the SIEF agreement).

25. It is recommended that detailed information on cost sharing should include a **breakdown of the costs of the studies** covered by the LoA, their respective value and the number of current and/or expected registrants.

26. It should be clearly described in the SIEF agreement (or where appropriate) 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.

27. The content of the **documents** that will be provided to the co-registrant upon reception of the payment of the LoA should be described.

28. Because SIEF members are liable for the information submitted by the lead registrants in their name in a joint submission it is not advised that SIEF members only receive the token to be part of a joint submission following the payment of the relevant compensation. If the CSR has been submitted jointly, members also need the information (e.g. exposure scenarios) to be able to provide adequate recommendations in their supply chain to handle the substance safely.

29. Instead, SIEF members should have **access to all information** submitted by the lead registrant on behalf of the joint submission that they paid for and that is necessary to understand and critically evaluate their specific situation. This information includes at least data according to Article 11(1) paragraph 2 of the REACH Regulation provided ideally via the reception of the IUCLID file.

This means that by paying a LoA in order to participate in the joint submission, the SIEF members should have access to the endpoint results for which they have paid as well as a copy of the robust study summaries, and study summaries if available. Further relevant information shall be available on request. Where companies will financially contribute to e.g. the Chemical Safety Report, they should also receive this information. What is covered by a LoA or other kind of contribution should be clearly described in the communication regarding the access to the joint dossier and the corresponding compensation.

30. Certain information might be **confidential** and access should only be granted to the legitimised SIEF members.

31. 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 SIEF Agreement should clearly indicate that the co-registrant still has to individually acquire rights on such data from third parties. Such a situation where the data and license package provided by the lead registrants/consortium does not cover all the registration needs of the co-registrants occurs whenever some data is owned by third parties that have not granted to the lead registrants/consortium the right to sub-license their studies to the co-registrants.

32. If requested, the **scientific justification** on the approach followed in the selection of data should be provided.

33. In case a co-registrant intends to **opt-out** for certain information (Art. 11(3) REACH), the respective co-registrant should first communicate with the lead registrant. In that case it is recommended that a reasonable time to react should be given to the lead registrant before taking any further step to accommodate this opt-out.

34. **Agreements** that provide the basis for invoices issued to co-registrants should clearly describe the type of costs being invoiced and their frequency (e.g. annual vs one-off costs). Invoices need to be structured in a clear and understandable way, providing a digestible and useful amount of detail.

c) ***Non-discrimination:***

The DCG would like to recall the following principles of non-discriminatory cost sharing:

35. The **cost sharing mechanisms** should be openly communicated and be applied to all SIEF members regardless of the differing times at which a co-registrant may have joined the joint submission. In principle, the model established for the 2010 registration deadline should continue to be applied for the 2013 and 2018 registration deadlines. It might be objectively justified to update the price of the Letter of Access according to indexation or to the different updates of the joint dossier (e.g. additional studies following dossier evaluation) but additional costs due to the simple fact of being a "late-comer" in the SIEF are discriminatory.

36. The SIEF agreement may also establish a **reimbursement scheme** based on the actual number of co-registrants which ensures equal sharing of the costs. This regime will need to consider if the number of SIEF members that have actually been granted an access to the joint dossier is higher (or lower) than the estimation initially used to calculate the amount of the shares. Then, the cost per member will decrease (or increase) and a partial reimbursement (or additional invoicing) may have to take place. However, the agreement may also consider the fraction of the SIEF assets needed to establishing a reserve fund for future purposes, such as testing after an evaluation decision etc.

37. Other ways of defining the final costs in a transparent way may also be considered in the case of lead registrants who had to prepare the registration dossier alone without any additional support.

38. The **final price** of the shared data cannot be the outcome of 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 cost of that data, and possibly the efforts to compile it.

39. **Consortium costs**, which are charged to the SIEF, must be clearly and demonstrably related to efforts which are required and in the interest of all SIEF members. Charging other consortium costs can be agreed only on an individual basis. To avoid disputes it is recommended that such an agreement is established at an early stage.

40. Even **if a registrant opts out** from information submitted by the lead registrant, the respective registrant is still part of the joint submission. Therefore the lead registrant must still provide that registrant with the REACH-IT token so that the registrant can confirm membership to the joint submission.

41. The REACH Regulation requires companies registering the same substance to submit their registration jointly. Nonetheless, if a company has initially registered individually outside the joint submission (e.g. at the beginning of the SIEF process when the lead registrant was not identified) and is subsequently seeking to remedy this situation by **entering the joint submission**, that individual registrant should contact the corresponding lead registrant, member of the consortium or other registrant to learn about the conditions. In most cases, this may imply the subsequent payment of the relevant compensation. When that registrant already possesses an own set of data (see point above), the registrant may still be asked to compensate a fair share of reasonable joint submission costs.

42. **Different treatment among SIEF members** must be strictly limited to situations that are objectively different and must always be justifiable.

II RECOMMENDATIONS TO CO-REGISTRANTS DURING THE COST-SHARING NEGOTIATIONS

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

- answer communications sent by the lead registrant/consortia as soon as possible;
- 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 to put in writing all the relevant aspects of cost sharing, either via the SIEF agreement and/or via clear and complete invoicing documents;
- ask for clarification of any misunderstanding with precise questions, in case of concern;
- ask the existing registrants which data is covered by the joint submission and what are the costs of this data before 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/consortia 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 registrants have to be treated in the same way;
- propose alternative solutions when negotiations are blocked, remain proactive and open in their communications;
- allow "late joiners" to raise circumstances that they perceive to discriminate against them and decide to address ECHA with a data sharing dispute or to seek legal advice from their associations;
- 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. According to the contractual arrangements in place in the SIEF, the parties may also attempt to settle any disagreement either by **arbitration** or via ordinary **national civil courts**.

ECHA's data sharing dispute mechanism is free of cost and does not require the involvement of a lawyer. In a case potential registrant considers that the existing registrants (be they represented by the lead registrant or any other representative) have not made every effort to reach an agreement, the data sharing **dispute mechanism available at ECHA** can be initiated. It is important to note, ECHA does not have a mandate to be involved in the negotiations as a third party (as it is the case of arbitration). The parties will be requested to submit their documentary evidence, based on which ECHA will make an assessment of the parties' efforts to reach an agreement in a fair, transparent and non-discriminatory way.

In case ECHA would make a decision favourable to the claimant, the claimant will be granted the permission to refer to the information contained in the lead dossier. The registrant having been the other party in the dispute will nonetheless have a legitimate claim to its share of the cost.

Lastly, when there is some reason to consider that 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