

DIRECTORS' CONTACT GROUP

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RECOMMENDATIONS ON SOUND SIEF MANAGEMENT

WHAT IS A SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF)?

All companies that pre-registered the same phase-in substance¹ become members of the respective SIEF². In a SIEF, they share two obligations: 1) share data on the intrinsic properties of the substance to avoid duplication of studies and 2) agree, if possible, on the classification and labelling of the substance. Specifically, SIEF members have the obligation to share all test data on vertebrate animals, react to requests for information and work collectively to identify and carry out additional studies or submit testing proposals when needed. In practice the SIEF is also the platform for organising the obligation to submit the registration jointly.

In addition to potential registrants, downstream users and any person or organisation holding data relevant to a phase-in substance can participate in the SIEF if they have identified themselves as a data holder and are willing to share their information.

SIEF members can be active members, taking a lead or being involved; or passive and even dormant members (see table below). The level of activity of each SIEF member needs to be viewed separately from the format in which the SIEF is organised as well as from the pathway by which an individual registrant chooses for joining the SIEF. In those cases in which the chosen form of organisation involves a consortium, registrants may either opt to join the consortium or to buy a Letter of Access (LoA) to the entire registration dossier or to buy such a LoA only to certain endpoints whilst being active in the SIEF regarding others. Considerations to be made when choosing between the first two of these pathways to join a SIEF are described in a separate DCG document³.

SIEFs have no prescribed legal form and they are independently managed by the involved enterprises. Neither the European Commission nor ECHA are involved in their operations. On the occasions of the previous registration deadlines in 2010 and 2013 and for practical reasons, the lead registrant as the main data holder typically took on the task of managing the SIEF. For the 2018 registration deadline, this may no longer be the case. Legally a SIEF has to remain operational at least until 1 June 2018.

¹ These are substances that either i) are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), ii) have been manufactured in the EU (including the countries that joined on 1 January 2007) but have not been placed on the EU market after 1 June 1992 or iii) qualify as "no-longer polymer".

² See Article 29 of the REACH Regulation.

³ A document "[Considerations to be made when joining an existing SIEF](#)" published on ECHA webpage.

In practice a SIEF will have to stay operational beyond 1 June 2018 to be able to respond to the continuous obligation of registrants to update their data as well as to accommodate subsequent co-registrants entering the market.

Key principles for SIEF management⁴

The principles of transparency, fairness, non-discrimination and not for profit are key for a sound SIEF management, and should be respected in all interactions.

Transparency: Provide information to your SIEF members and potential registrants of the same substance on the following:

- Scope of the substance covered by the SIEF (substance identity profile)
- Contact information regarding lead registrant or SIEF facilitator⁵, if the latter is relevant
- “What you get” for a Letter of Access (LoA) (e.g. usually right to refer to data for REACH registration purposes, template IUCLID, CSR, SDS as applicable)
- Cost structure of the fee: fixed part, variable part depending on number of registrants covered, tonnage (band). Details of the fee/cost calculation and the budgets are to be made available (see DCG document “Fair, transparent and non-discriminatory cost sharing in SIEFs”).

You can provide this information e.g. on a publicly accessible website or a dedicated website for potential registrants only, for instance linked to the pre-SIEF pages in REACH-IT.

Fairness: Costs are to be shared equally among members/LoA holders having to fulfil identical data requirements due to their relevant tonnages or tonnage bands and the number of registrants. **It should be ensured that LoA enquirers are always guided to the cheapest financial option for them to fulfil their REACH requirements.** There is a tipping point at which consortium membership becomes more cost effective than the purchase of individual LoAs⁶. That should be explained to the LoA enquirer and worked through by both parties to determine the most cost-effective option for the enquirer.

Non-discrimination: All companies intending to register a substance can become active members of the respective SIEF / consortium and/or alternatively buy a LoA. Whilst a consortium remains active, **its doors should remain open to any SIEF member** that wishes to sign up to the terms of the consortium agreement and join.

Not for profit: The membership fees of the SIEF or consortium and revenues from LoAs count towards covering budget needs for preparing and maintaining registration dossiers. Surpluses can be carried over to the next year(s) to cover future activities or can be reimbursed at some point in time.

⁴ For further detail on these principles, especially in relation to cost-sharing, see the DCG document on “Fair, transparent and non-discriminatory cost sharing in SIEFs” published on [ECHA webpage](#).

⁵ The role of the lead registrant is defined in the REACH Regulation. This role contains submitting the joint parts of a registration dossier for a given substance on behalf of all registrants of that substance. The role of a SIEF facilitator, on the other hand, consists of taking care of the practical organisation, administration of and communication within a SIEF. These roles can be taken up either by the same actor or by different actors (companies).

⁶ See DCG document on “Considerations to be made when joining an existing SIEF” published on [ECHA webpage](#).

Practical start of the SIEF activities

The joint submission obligation implies that the SIEF has to agree on the various tasks to be undertaken, as well as on the rules for the general management and on financial terms. This is usually done through a group composed of active members of a SIEF or of a consortium (established by a legal act) which can be defined as a temporary association of two or more legal entities in view of preparing and submitting joint REACH registration dossiers. Whatever the **composition of the SIEF**, rules should be agreed on, respecting the four principles of transparency, fairness, non-discrimination and not for profit. In order to get a SIEF organised in the most efficient way before the work on compiling the registration dossier can start, the following steps are recommended:

- The SIEF should appoint a SIEF facilitator and subsequently a lead registrant.
- As a good practice, it is recommended to ask SIEF members which status they want to have within the SIEF according to their desired level of commitment (leading/involved/passive/dormant). Leading and involved members are also referred to as “active” members.

Leading	Involved	Passive	Dormant
Usually owning (part of) the data and involved in all aspects of SIEF management	Usually not owning any data but actively involved in remaining aspects of SIEF management (e.g. discussions on data selection, model of cost sharing, etc.)	Having pre-registered and expressed the intention to register by 2018, however interested mainly in obtaining the letter of access only (without further involvement in SIEF activities)	Having pre-registered in 2008 but without re-confirming yet the intention to register by 2018

- A communication method/platform should be agreed. This can be for example a restricted web site for SIEF members or simple emailing, depending on the size of the SIEF.
- Each SIEF or consortium may decide on its own rules. It is recommended to prepare a SIEF or Consortium Agreement which clearly establishes its operational rules. See an example of SIEF Agreement⁷ and recommended DCG guidance on cost and data sharing (a document “Fair, transparent and non-discriminatory cost sharing in SIEFs” published on [ECHA webpage](#)). EU competition rules should be complied at all times. It is recommended to make the SIEF or Consortium Agreement publicly available on a website.
- A method for tracking the SIEF decisions should be established. They should be properly recorded, approved by the SIEF’s governance according to pre-agreed rules (e.g. by a Steering Committee or by its active members) and made readily accessible to all SIEF members (e.g. on a dedicated SIEF website).
- It can also be considered to compensate the SIEF and/or consortium facilitator for exercising these management tasks. Whenever this is done, the pricing of such compensation should reflect the transparency, fairness, non-discrimination and not-for-profit principles.

⁷ Cefic model SIEF agreement can be accessed from a link on page two of the Cefic recommendation on Letter of Access: http://cefic.org/Files/Publications/Cefic_recommendation_letter_of_access_FINAL.pdf

- It is recommended that active SIEF members or the consortium conduct a survey among all pre-registrants to identify potential co-registrants for the 2018 registration deadline. Based on the feedback received, fair terms and conditions for the Letter of Access (LoA) for each respective tonnage band can be developed to be agreed upon according to pre-agreed rules (e.g. by formal vote). For practical reasons, it is recommended to set a reasonable deadline for the feedback from SIEF members. The SIEF should confirm the registration duty for the substance.
- A decision on whether to hire a consultant for joint dossier preparation or not should be made.⁸

Preparation of a joint REACH registration dossier

A joint submission is mandatory, even if one member chooses to opt-out from certain or all data requirements. An opt-out will proportionally reduce the necessary financial contribution of the concerned member.

It needs to be ensured that the SIEF obligations are fulfilled and that all SIEF members are at a minimum kept aware of the content and timelines related to the registration dossier preparation. In that respect SIEF members should be provided with all necessary details so that they can understand and exclude relevant liability risks. All SIEF members share the responsibility that a compliant joint dossier can be submitted before the registration deadline.

Registrants joining the SIEF need to verify the sameness of their substance in accordance with its substance identification profile (SIP) or equivalent information. A proper record of the SIEF members' replies should be kept to allow for tracking back this information.

The SIEF has to organise the data sharing which is typically organised in subsequential steps of which the most prominent are the following: data inventory; data selection; data gap analysis; data collection; cost sharing model.

- An email can be sent to all SIEF members informing them of the identification of the substance and asking them for available existing data. The group of active SIEF or consortium members should agree on the data gap analysis, on how to address each endpoint (carrying out missing studies, literature review, expert statement, waiving, etc.), on the appropriate sample to be selected for testing (composition, characterisation, etc.), on the laboratory(ies) and possible external consultants to be selected for the preparation of the dossier. It is recommended to obtain the formal agreement (by vote) of the active SIEF or consortium members in writing on the various steps and properly keep a record of all the decisions.
- The group of active SIEF or consortium members should organise a consultation of the SIEF members to agree on the classification and labelling of the substance. It is recommended to do this through an email communication or/and by making the information publicly available on the dedicated website.
- It is necessary to consult the group of active SIEF or consortium members, as well as the legal entities that have declared their intention to register the substance (whatever the registration deadline) to agree on the common part of the registration dossier which will be jointly submitted.
- It is recommended to jointly prepare the CSR, even if parts of it may be submitted individually by each co-registrant. If the CSR is jointly prepared, the list of uses to be covered should be made publicly available.

⁸ See DCG Checklist to hire a good consultant published on [ECHA webpage](#).

- Once agreed upon, the terms and conditions for the LoA, the rights granted by the LoA, a template LoA agreement, the LoA costs, as well as a description of the exact content of the LoA package should be made openly available (e.g. on a dedicated website).
- Once the joint dossier is submitted by the lead registrant, this should be communicated to all SIEF members, which can then submit their own member dossier after they take all necessary steps to have the right to join the joint submission (e.g. joining the consortium, buying a LoA).
- The system to deliver LoAs should remain in place also beyond 1 June 2018 to accommodate subsequent new co-registrants and until the data no longer is subject to cost sharing according to the "12-year rule" (Article 25(3) of REACH).
- A system for keeping the dossier up-to-date and for responding to regulatory requests should be established before submitting the registration.

Communication and transparency

- It is recommended to openly communicate and be transparent by making available at all times the following documents: SIEF decisions, agreed substance identification profile, registration plan and timeline, SIEF or consortium agreement, membership terms and conditions, regular updates on the work developments, as well as updated contact details.
- It is recommended to make available an explanation of the content (e.g. usually right to refer to data for REACH purposes, template IUCLID, CSR, safety data sheet, etc.), as well as the terms and conditions for the Letter of Access, as soon as possible. (See DCG document on "Fair, transparent and non-discriminatory cost sharing in SIEFs" published on [ECHA webpage](#)).