

# **DIRECTORS' CONTACT GROUP**

FINAL (4 June 2014)

## **CONSIDERATIONS TO BE MADE WHEN JOINING AN EXISTING SIEF**

Below are some considerations to be borne in mind when future registrants (primarily in the 1–100 ttT band) are looking at ways to take advantage of work already done by larger tonnage registrants (with 2010 and 2013 deadlines).

It is important to recognise that each consortium is unique in its structure, financing, charges and deliverables. Individual approaches are also largely dependent on the level of knowledge and/or formal datasets (such as EU recognised Risk Assessments) that existed back in 2008 when some consortia were set-up.

While the criticality of the substance to the business of the co-registrant should determine whether to join an existing consortium or to take a lower profile in the SIEF and purchase a Letter of Access (LoA), at this stage in the registration process, it is most likely that purchasing an LoA will be a sufficient (and most likely less expensive) option.

Joining a SIEF is not only about submitting a dossier, but represents a commitment to further update the dossier and to remain responsible for it even beyond 2018.

It is considered best practice that:

- SIEF members need to have transparent information on the data access options open to them and the fees involved (full membership or LoA purchase). Depending on individual consortium structures, often there is a tipping point at which consortium membership becomes more cost effective than the purchase of individual LoAs.
- Whilst a consortium remains in existence, it should be open to any SIEF member that wishes to sign up to the terms of the consortium agreement. Such an agreement has to respect competition law.
- Consortium websites (which could be those of the commodity association or entity managing the consortium) should be used to make this information available easily and with the minimum of administrative burden (and therefore cost to all parties).

Before joining a consortium or purchasing a LoA, the potential co-registrant should ensure that the substance covered by the SIEF is the same substance as he produces/imports and intends to register. Potential co-registrants need to justify "sameness" of the substances based on their own data and the substance identity description provide by the SIEF/consortium.

Joining a SIEF via buying a LoA...	...via active consortium membership
Would most likely be the solution involving the lowest costs to have access to the data needed to support the own REACH registration.	Opportunity for active participation in work of the consortium. However, most likely requires greater financial outlay and human resource involvement for the preparation of the joint part of the REACH registration dossier and for subsequent updates.
Less need to invest in internal or external (consultants) resources, but, to a large extent, it requires understanding and acceptance that the consortium's joint dossier is appropriate for the future registrant's business needs (substance identity, exposure scenarios, etc.)	Participation in decision-making and potential to influence Consortium management, work plan, budget, scientific testing, exposure scenarios, etc.
The LoA grants a 'right to refer' to the data package necessary for REACH registration (and no other purposes) as contained in the Lead Registrant's (LR) technical dossier.	Ownership of consortium-generated data, and/or access to data and full studies (i.e. more than robust study summaries), and/or right to use the data for purposes other than REACH (the latter benefit can vary by Consortium).
Receive components and services specified in the LoA contract. These cover, at least, the name of the joint registration, the token to become member of the joint submission and the information jointly submitted by the LR on behalf of the co-registrants. Additional LoA deliverables vary by provider e.g. information from the joint dossier in a IUCLID or other format, guidance to submit the member registration dossier, Chemical Safety Report (CSR), agreed C&L, template Safety Data Sheet (SDS), etc.	Receive the same as SIEF/LoA (see box on left), plus the full, joint part of the IUCLID dossier and CSR.
Limited assistance with overall REACH understanding & process.	Usually, the consortium services its members with detailed technical assistance and guidance.
Usually a LoA is specific to one substance and one legal entity.	Membership based on legal entity or may also cover group membership i.e. company + affiliates (provided this is foreseen in the consortium agreement and the group has declared all relevant production volumes as these are the basis of member financial contributions to the consortium).