

concaawe



# Working in SIEFs: main tasks

ECHA Lead Registrants Workshop, Helsinki  
2<sup>nd</sup> & 3<sup>rd</sup> February 2012

**S. Bornstein**

Warning to the reader: the information provided in this presentation is to not be regarded as legal advice.

1.Key messages

2.Practical steps to registration

3.The LR role in the SIEFs

4.Key tasks for co-registrants

5.Conclusions



**Thousands of registrants have already submitted their registration by the 2010 deadline: benefit from their experience by using existing structures, documents & support**

- ▶ Don't re-invent the wheel to register efficiently!

**REACH legislation and registration requirements are complex and very specific: take time to get familiar with them ahead of the deadline**

- ▶ Plan your work and start early!

**Participation in SIEFs is mandatory for all registrants and the tasks required need to assemble diverse skills: technical, management and administrative. Make sure you either have these internally or contract them externally.**

- ▶ Don't wait to identify these skills!

**Tasks within a SIEF vary depending on SIEF members' roles: LR, co-registrants, data owner, SFF. One Entity may act in several of these roles for different substances.**

- ▶ Understand precisely what is expected from you and in what role!



1. Find out if a SIEF has already been formed for your substance (pre-SIEF pages of REACH IT)
2. Contact the consortium/SFF to verify that you are registering the same substance as the other SIEF members (sameness check)
3. Sign a SIEF Agreement to define the boundaries of your collaboration with other SIEF members
4. Find out if your substance has previously been registered (ECHA's list of appointed LRs) or if a Lead Registrant needs to be appointed
5. Understand the implications of being Lead Registrant yourself: what is required for preparing the joint submission?



6. Identify where (and when) you can **obtain the information** you need to prepare your registration:

Typical questions:

- Availability of analytical data on your substance
- Availability of data/studies (involving animal vertebrate or not), who owns them and how they can be shared,
- Has a consortium been formed and what are the costs to be shared
- Cover respective involvement of the parties contractually (SIEF Agreements)
- Existence of a joint dossier and scope (CSR)
- Planned date for creating the JSO
- Are your uses covered by the risk assessment
- Is a Communication Platform existing and how can you access it



**Under the CONCAWE operating mode for Petroleum Substances SIEFs, the role of the LR is limited, CONCAWE is supporting LRs in most of their REACH duties.**

### **What is expected exactly from the LR?**

- When contacted to take the role, read the terms of the (tri-partite) Lead Registrant Agreement to be signed with CONCAWE (and later with registrants joining the JSO)
- Identify itself to ECHA and create the JSO
- Download the dossier in IUCLID format for the joint parts of the registration dossier and create its individual parts
- Submit the dossier to ECHA and report to CONCAWE
- Obtain the token needed by other registrants to join the JSO and ensure it is adequately renewed and shared with CONCAWE
- Monitor feedback received (REACH IT mailbox) on dossier submitted and ensure follow-up actions required post-registration are timely taken



## What does CONCAWE do to assist the LR?

**CONCAWE supports the LR in two capacities: as SIEF Formation Facilitator (SFF) and as Licensor (Lic) of data used for the Risk Assessments required in the Registration Dossiers.**

### In practice

- Survey pre-registrants about their registration intentions (SFF)
- Call for available data, analyse relevance and negotiate data sharing terms & costs on behalf of the active SIEF members (Lic)
- Set up a contractual relationship with active SIEF members (obtain LoA & IUCLID file, cost compensation): Licence Agreement and SIEF T&Cs (Both)
- Ensure all co-registrants accept the terms of the LR Agreement (Both)
- Make (common parts of) dossiers available via its SIEF platform (Lic)
- Share with co-registrants status of Joint Submission (SFF)
- Support co-registrants in their registration (technical, admin) (Both)
- Distribute tokens and JSO name (SFF)
- Share post-registration information with co-registrants (SFF)



## Recommendations

LRs can rely on support of SFF / formed Consortium to obtain practical guidance, information on available tools and access to data

- LRs should take the time to understand the contractual relationship established with other SIEF members who intend to register (respective roles, responsibilities and liabilities )
- LRs should ensure data sharing and cost sharing obligations are being taken care of within the SIEF **prior** to submitting their registration: understand what SIEF operating structures are effectively taking care of (identification of existing data, data sharing terms, terms for co-registrants to obtain access rights to these data).
- Communication within the SIEF does not rest on the LR's shoulders exclusively: Tools are available to ensure information is shared prior to registration and thereafter.



## What co-registrants should do:

- Reply to surveys on registration intentions (e.g. response rate after 1 month: less than 10% !)
- Find out who is the Lead Registrant / SIEF Formation Facilitator
- Sign a SIEF Agreement and ensure it provides access to the information required to register & which must be shared under REACH
- Understand the costs involved: several types of activities conducted within a SIEF trigger costs, which are to be shared in a fair, transparent and non-discriminatory manner between all SIEF members (data, dossier preparation, SIEF management & communication)
- Data owners should make themselves known early so that the SIEF can assess the relevance of their data for the registration dossier.



## Recommendations:

Make sure your pre-registration is active in REACH IT and you contact e-mail is up to date (use generic e-mail recommended)

- If you are not contacted by the LR/SFF, take contact yourself and ask about the availability of LoA and Joint submission status
- Visit existing (industry association) web sites where the SIEF processes are extensively documented
- Get familiar with REACH-related IT Tools needed to register successfully (software applications, plug-ins, communication platforms)
- Remain active in the SIEF for post-registration activities, if information about your registration changes, update it pro-actively and don't forget to inform the SFF/LR if necessary (e.g. legal entity name, contact details)



- **Tasks to accomplish in a SIEF are significant but registrants are not on their own: turn to your National Help Desks, Industry Associations or ECHA**
- **Make sure you are in compliance with EU Competition Rules at all times while exchanging information within SIEFs and that your Confidential Business Information is protected**
- **Bear in mind that once your registration is submitted, you are not done with REACH. It is only the first step! Ensure that you remain actively informed of activities going-on in the SIEF post-registration in order to maintain your registration compliant.**



**Thank you for your attention !**

