REACH 2018 SME Workshop

Road to a Successful Registration
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Experiences of a Co-registrant

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Definitions

Before starting: are you sure to be a SME? Check the Commission Recommendation of 6 May 2003, in particular if you are an autonomous enterprise !

Let's review some definitions … to better understand who are the actors with whom we must work together as co-registrants:

- **Pre-SIEF members**: pre-registrants who indicated the same substances identifiers (REACH-IT groups them into a pre-SIEF); the pre-SIEF includes both "Active" and "Inactive/Dormant" members
- **SIEF members**: as soon as pre-SIEF members agree on the sameness of a substance and start with the data-sharing process, classification and labelling discussion, Lead Registrant nomination, etc. These processes involve only "Active" members
- http://www.reachcentrum.eu/Consortia%20Documents/P-I152/Other/P-I152_EC249-079-5_SIEF_coding.pdf

Definitions

- **Facilitator**: is not provided by the REACH Regulation
- It is an *unofficial* role but it has been included in the pre-SIEF
- Art. 29 states that the aim of each SIEF is to **facilitate** the exchange of the information on the substance (sameness, C&L, studies, etc.)
- The Facilitator is a voluntary role that gathers the needs of pre-registrants and guides them towards the SIEF's formation
- The Facilitator can organize the first meetings (physical, virtual, etc.) between the pre-registrants and guide them towards choosing the Lead Registrant (€ compensation?)
- The Facilitator takes care of the practical organization, administration and communication within a SIEF, could subsequently be the LR (but not necessarily)

Role

- **Lead Registrant**, excluding the *official* definition provided in the Regulation, could be the person (or company) that manages the SIEF
- Sometime, in the SIEF there is a small group of companies (leading) that are involved in all aspects of SIEF management
- **Before** the dossier submission, the Lead Registrant should help the SIEF members to be active and involved in the registration process
- Only **after** the dossier submission he becomes LR *in charge:* ECHA accepts only one dossier/substance

Role

- **Consortium Manager** is the person (or company) that manages the registration process
- Sometime the LR coincides with the Manager
- Usually, the Consortium Manager is an expert consultant (or even a big consultancy company)
- Please note that while the Lead Registrant Role concerns the SIEF (and is an official role), the Manager works within one or more Consortia

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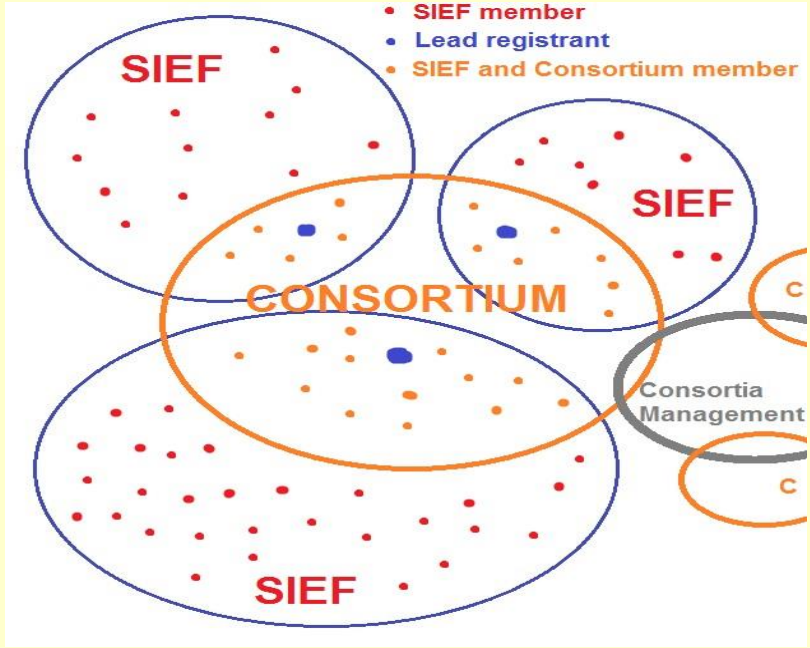

Consortium vs SIEF

	Consortium	SIEF
Substance(s)	Usually more than one	One
Participants	Only: Leading, Registrants, Actives, Data holders	Also: Inactives, potential registrants
Costs/Expenditures	YES	Usually NO
Director/Management	YES	Usually NO
Facilitator	NO	YES / NOT YET
Lead Registrant	YES	YES / NOT YET
Ask for money	Could be	Absolutely NOT
External Consultant(s)	Usually	Could be dangerous ☺
Contacts between participants	Frequent and safe	Rare and difficult
ECHA communications	NO	YES
Email addresses	Updated and secure	Often no longer active

In the SIEF

- Some consultancy companies have pre-registered the whole Einecs database
- Sometimes this is attempted in order to ask for money without offering any service in return
- The facilitator may charge a fee (agreed before) only if he really does his job (organizing meetings, planning data gap analysis, etc.)
- Be careful in case pre-sief members ask for money
- Last “late pre-registration” (art. 28) by the end of May 2017 (art. 23 - 1÷100 tpa)

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Already Registered

- Sameness (rules, criteria, analitycal, etc.)
- Letter of Access details (agreement)
- Chemical Safety Report: provided or not?
- Safe Uses: provided or not?
- LoA price
- Token and Join Sumbmission name
- Good familiarity with the software (Iuclid 6) to submit the own registration
- Alternatively: a good consultant who can do all these things

Not yet registered

- Before starting the learning process …
  - Check if a Facilitator is present in the pre-Sief
  - Check if a Lead Registrant is present in the Sief
  - Check if there is a Consortium that manages the registration process

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Hypothetical Scenarios

	1	2	3	4	5	6
The substance has been registered?	YES	YES	NO	NO	NO	NO
Does a Consortium work?	YES	NO	YES	NO	NO	NO
Is there a (nominated / elected) Lead Registrant?	YES	YES	YES	YES	NO	NO
Do we find a Facilitator?	n.a.	n.a.	n.a.	n.a.	YES	NO

1) Registered Substance, Consortium & LR

- The above «mask» helps the co-registrants within the pre-sief
- Scenario #1 is the best case
- It is possible to find: contacts, information, links, etc.
- All the subsance information are available in the ECHA «search for chemical» web-page https://echa.europa.eu/information-on-chemicals

2) Registered Substance & Lead Registrant

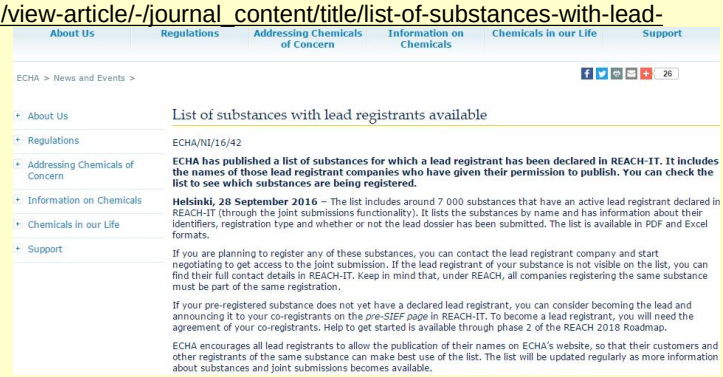
- Scenario #2 is even easier to manage
- In this case you have to contact directly the Lead Registrant (contacts availabe in the pre-Sief mask)
- All the subsance information are available in the ECHA «search for chemical» web-page https://echa.europa.eu/information-on-chemicals

3) Consortium & elected LR

- In the pre-SIEF pages it is possible to find some useful information
- Sometimes it might be more advantageous to join the consortium rather than simply buying the LoA
- Usually the “Facilitator” is either LR or Consortium manager contact

4) There is only the Lead Registrant

https://echa.europa.eu/view-article/-/journal_content/title/list-of-substances-with-lead-registrants-available



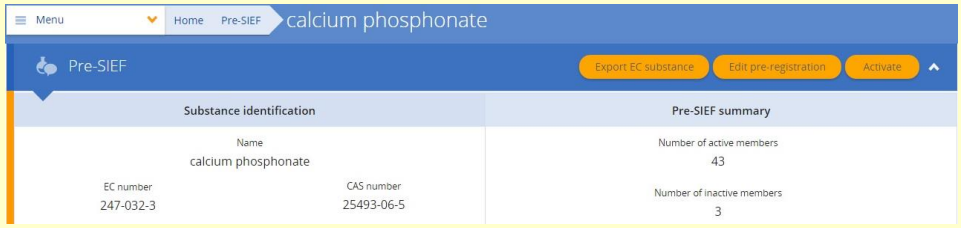
- You have to contact the LR to verify:

1) If it is possible to create a Consortium (sameness information needed)
2) If he is already preparing the dossier and he is only looking for other companies to share the expenses

5) There is only the Facilitator

- First you must try to understand the *kind* of Facilitator you're dealing with …
- … it could be a Company that wishes to become Lead Registrant ☺
- But it could also be a "consultant" looking for easy money! ☹
- The registration deadline is "behind the corner" and there is no time to lose
- Be careful if the facilitator (potential LR) is not active, has not already contacted other SIEF members, has not started any discussion within the SIEF for sameness and/or for the data gap analysis …
- …it may look like scenario #5 but really it is the #6

6) The Worst Case



- Download the pre-SIEF member list (name, address, phone and email)
- Check for larger companies; contact and verify if they are working to form the SIEF and if a potential Facilitator is already active
- Try to send emails to the other pre-SIEF members
- Check for sameness and substance identity and supporting analitycals
- If the substance is very important for your needs, consider to become the Facilitator and ask to the pre-SIEF members to be elected as LR
- ... and the game begins!

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Conclusions (1)

- Also the joint submission dossier is not easy to prepare
  - Either you download the IUCLID 6 software and fill it…
  - …or you will have to appoint an external consultant
  - but even in this last case your active participation will be required

Conclusions (2)

- Beware of consultants:
  - that do not ask for your business size
  - that do not investigate on the nature of the substance that you manufacture / import
  - that do not inquire about the quantities you manufacture/import

ECHA CHECKLIST TO HIRE A GOOD CONSULTANT: https://echa.europa.eu/documents/10162/13559/dcg_consultant_checklist_en.pdf/e6600a27-b2d6-447e-abce-95e6e2e1e26a

Conclusions (3)

- Before starting the joint-dossier preparation a consultant must be able to inform you about the following:

  1) ECHA fee
  2) Letter of Access cost and how to buy it
  3) Analytical cost
  4) Consultant honorary

  (he may ask a fee to collect these information)

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Thank you for your attention

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