

# REACH 2018 SME Workshop

## Road to a Successful Registration

Vienna, 9 March 2017

## Experiences of a Co-registrant



Co-organized by



Mariano ALESSIO VERNI - SILC Fertilizzanti Srl

1

# Contents

- Definitions and Roles
- SIEFs vs CONSORTIA: differences
- What a co-registrant must know
- How to manage the co-registration process
- Conclusions

SILC Fertilizzanti Srl



2

- **Definitions and Roles**
- SIEFs vs CONSORTIA: differences
- What a co-registrant must know
- How to manage the co-registration process
- Conclusions

## 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](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)

SILC Fertilizzanti Srl



5

# 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

SILC Fertilizzanti Srl

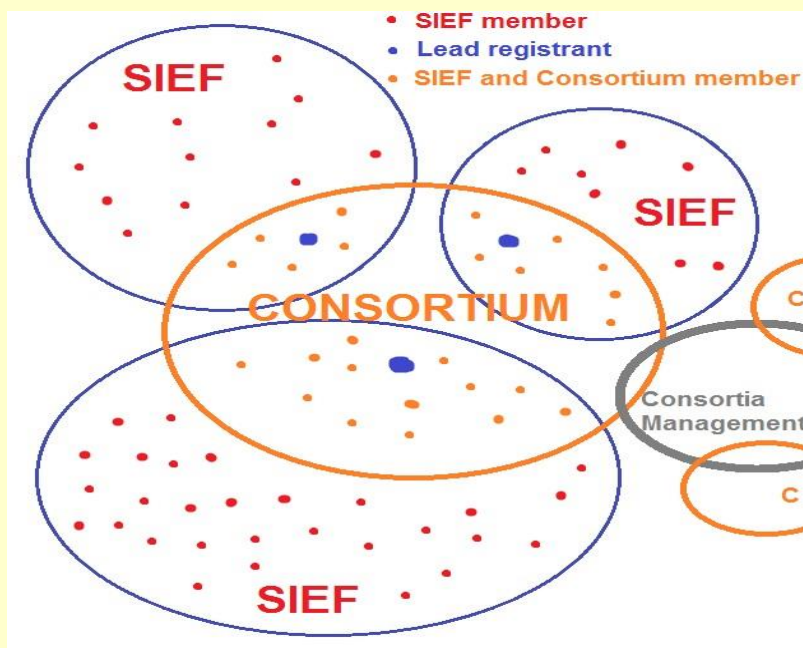


6

# 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

- Definitions and Roles
- **SIEFs vs CONSORTIA: differences**
- What a co-registrant must know
- How to manage the co-registration process
- Conclusions



## 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 Eines 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)

- Definitions and Roles
- SIEFs vs CONSORTIA: differences
- **What a co-registrant must know**
- How to manage the co-registration process
- Conclusions

# Already Registered

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

SILC Fertilizzanti Srl



# 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

SILC Fertilizzanti Srl



- Definitions and Roles
- SIEFs vs CONSORTIA: differences
- What a co-registrant must know
- **How to manage the co-registration process**
- Conclusions

## 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 substance 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 available in the pre-Sief mask)
- All the substance information are available in the ECHA «search for chemical» web-page  
<https://echa.europa.eu/information-on-chemicals>

### 3) Consortium & elected LR

Substance identification		Facilitator contact information	Pre-SIEF summary	Information from the SIEF formation facilitator/nominated lead registrant
Name dipotassium phosphonate  EC number 236-809-2 CAS number 13492-26-7		Contact details Mariano Alessio Verni @mariano@silcfertilizzanti.it	Number of active members 157 Number of inactive members 14	PPC Consortium manages the registration process of this products family. Please visit <a href="http://www.italianchemicals.com">http://www.italianchemicals.com</a> to receive more details. XXX is the Lead Registrant Registration expected in 2018

- 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

SILC Fertilizzanti Srl



19

### 4) There is only the Lead Registrant

[https://echa.europa.eu/view-article/-/journal\\_content/title/list-of-substances-with-lead-registrants-available](https://echa.europa.eu/view-article/-/journal_content/title/list-of-substances-with-lead-registrants-available)

About Us	Regulations	Addressing Chemicals of Concern	Information on Chemicals	Chemicals in our Life	Support
ECHA > News and Events >					
• About Us	<b>List of substances with lead registrants available</b>				
• Regulations	ECHA/NI/16/42				
• Addressing Chemicals of Concern	<b>ECHA has published a list of substances for which a lead registrant has been declared in REACH-IT. It includes the names of those lead registrant companies who have given their permission to publish. You can check the list to see which substances are being registered.</b>				
• Information on Chemicals	<b>Helsinki, 28 September 2016</b> – The list includes around 7 000 substances that have an active lead registrant declared in REACH-IT (through the joint submissions functionality). It lists the substances by name and has information about their identifiers, registration type and whether or not the lead dossier has been submitted. The list is available in PDF and Excel formats.				
• Chemicals in our Life	If you are planning to register any of these substances, you can contact the lead registrant company and start negotiating to get access to the joint submission. If the lead registrant of your substance is not visible on the list, you can find their full contact details in REACH-IT. Keep in mind that, under REACH, all companies registering the same substance must be part of the same registration.				
• Support	If your pre-registered substance does not yet have a declared lead registrant, you can consider becoming the lead and announcing it to your co-registrants on the pre-SIEF page in REACH-IT. To become a lead registrant, you will need the agreement of your co-registrants. Help to get started is available through phase 2 of the REACH 2018 Roadmap.				
	ECHA encourages all lead registrants to allow the publication of their names on ECHA's website, so that their customers and other registrants of the same substance can make best use of the list. The list will be updated regularly as more information about substances and joint submissions becomes 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

SILC Fertilizzanti Srl



20

## 5) There is only the Facilitator

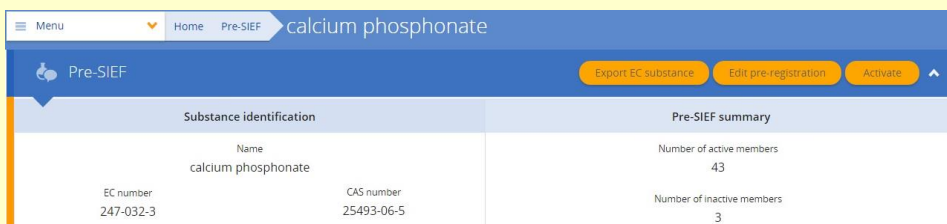
- First you must try to understand the *kind* of Facilitator you're dealing with ...
- ... it could be a Company that wishes to become Lead Registrant 😊
- But it could also be a “consultant” looking for easy money! 😞
- The registration deadline is “behind the corner” and there is no time to lose
- Be 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

SILC Fertilizzanti Srl



21

## 6) The Worst Case



Substance identification		Pre-SIEF summary	
Name	calcium phosphonate	Number of active members	43
EC number	247-032-3	Number of inactive members	3
CAS number	25493-06-5		

- 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 analyticals
- 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!

SILC Fertilizzanti Srl



22

- Definitions and Roles
- SIEFs vs CONSORTIA: differences
- What a co-registrant must know
- How to manage the co-registration process
- **Conclusions**

## 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](https://echa.europa.eu/documents/10162/13559/dcg_consultant_checklist_en.pdf/e6600a27-b2d6-447e-abce-95e6e2e1e26a)

SILC Fertilizzanti Srl



## 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)

SILC Fertilizzanti Srl





Thank you for your attention

Mariano ALESSIO VERNI' – SILC Fertilizzanti srl

27