



# What to bear in mind when becoming a Lead Registrant

**The clock  
is ticking**



**Countdown** 01 83 10 16 08  
30 11 2010 y d h m s



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# INTRODUCTION

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- **Remember the aims of a SIEF:**
  - Facilitate data sharing for the purpose of registration
  - Agree on classification & labeling
  - Prepare joint submission of a registration dossier
- **Participation in a SIEF is mandatory for all pre-registrants**
- **Industry – not ECHA - is fully responsible for SIEF organization**
- **A SIEF is not a legal entity or a consortium**
- **SIEF participants should set clear priorities and prepared to accept compromises**



# The Challenges

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- **There is no generally accepted guidance for SIEF organization and administration**
- **Number & size of SIEFs are unexpectedly high**
- **Still many SIEFs have no LR or the LR is not accepted**
- **The preparation phase for a SIEF to become operative can take months**
- **REACH requirements but also constraints like competition law must be taken into account**
- **Potential liability issues can be an obstacle to assume LR responsibility**



## Cefic Recommendations for LRs

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- ✓ **Nominate yourself as LR** *preferably* if you are a 'major player', own data and are prepared to manage the SIEF until 1 June 2018 or even longer
  
- ✓ **By-pass 'unwanted' SFFs**
  - ask these SFFs to step down from their nomination
  - inform them they will be by-passed if they continue to block the SFF box
  
- ✓ **Consult the SIEF on your nomination as LR**
  - Announce your candidature and set a deadline for a response
  - Make clear that 'silence means agreement'
  - Inform ECHA after your appointment using the web form<sub>4</sub>



## Cefic Recommendations for LRs

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- ✓ **Send out survey on 4 codes:**
  - Leading – involved – passive - dormant  
to *all* SIEF members
  
- **Set clear deadline for replying:**
  - Again: *'No answer' is assumed to mean 'dormant'*
  
- **Group the SIEF members** into the 4 categories according to their code



## Cefic Recommendations for LRs

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- ✓ **Keep the SIEF regularly informed on regular intervals**
  - The entire SIEF should be informed about the progress of the SIEF preparation for the the joint submission to be in line with the REACH obligations and avoid liability issues
  
- ✓ **Keep an open communication channel with the SIEF**
  - It is strongly recommended to establish a **single point of contact for the SIEF** and make this contact point known to all SIEF members

# Cefic Recommendations for LRs

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- ✓ **Keep the SIEF distribution list up-to-date**
  - Download the pre-SIEF XML file from REACH-IT regularly e.g. to take account of late pre-registrants
  - Make sure that companies joining from other SIEFs are also integrated
  
- ✓ **Keep old versions of software for SIEF communication**
  - Some SIEF members may be unable to open files if you are using new versions or updates



## Cefic Recommendations for LRs

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- ✓ **The prerequisite for a SIEF:  
agreement on substance identity**
  - The LR may send a **Substance Information Profile (SIP)** to the SIEF members
  - SIP available from Cefic website
- ✓ **Agree on SIEF operating rules**
  - Cefic recommends to use the Cefic SIEF model agreement – a contractual framework for the SIEF via a contract between the SIEF members
  - Without a formal SIEF agreement the LR may face liability problems and financial claims
  - Document the process of sending and receiving agreement to/from SIEF members

# Cefic Recommendations for LRs



**Agree on the scope of the Joint Submission and communicate within the SIEF**

## **Joint Submission**

- Classification & Labelling
- Test data summaries
- Test proposals

## **Joint or Separate Submission**

- Guidance on safe use
- Chemical Safety Report \*)

## **Separate Submission**

- Identification of registrant & substance
- Info on manufacture & use
- Exposure information (1-10 t/a)

\*) Individual submission of CSR permitted but may result in substantial workload for individual registrants



## Cefic Recommendations for LRs

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- ✓ **Set up an efficient system for invoicing and payment usable until 2018**
  - Inform the accounting department about the upcoming REACH related financial transactions
  - Consider to set up a separate legal entity and bank account for SIEFs transactions
  - Or: consider outsourcing to a service provider
  
- ✓ **Collect existing data**
  - Identify data gaps a.s.a.p.
  - Check availability of data 'outside' the SIEF
  - Prepare testing proposal if gap is not closed
  - Use standard template for requests



## Cefic Recommendations for LRs

- ✓ **Prepare Joint Submission in REACH-IT**
  - Provide name of Joint Submission and token to those SIEF members having fulfilled their obligations
  - Encourage SIEF members to sign-up to this Joint Submission in REACH-IT
  
- ✓ **Share information on Classification & Labeling**
  - It is highly recommended that all SIEF members (even without intention to register!) are informed about the agreed harmonised classification and are invited to join the joint notification\*

*\* Details on how to perform a joint notification are still under discussion with ECHA*

## Cefic Recommendations for LRs



- ✓ **Make sure your dossier passes all elements of the completeness check:**
  - ‘Business rules’ for format / technical / administrative reasons
  - Technical Completeness Check (TCC)
  - Financial check: payment of registration fees



**Attention:** *If dossier is deemed uncomplete, ECHA will set a deadline to submit missing information. Failing to do this, implies new registration dossier (and new registration fee) and may imply the ceasing of manufacturing and importing activities!*



## Cefic Recommendations for LRs

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- ✓ **Take into account future updates of the Registration dossier e.g.:**
  - Follow-up on test proposals
  - Request for additional information
  - Newcomers
  - Update of CSR following outcome of tests
  - SIEF can be operative until 2018 + 4 years



## Cefic Recommendations for LRs

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- ✓ **Cefic check-list is intended to provide SIEF members with an overview of all the tasks that need to be carried out in a SIEF**
- ✓ **The list includes the SIEF membership categories that need to be involved in each of the tasks as well as corresponding supporting documents**
- ✓ **See also the proposed Cefic recommendation for SIEF timing**

*See the Cefic website!*



## For further information

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➤ **Cefic Guidance on SIEFs:**

<http://www.cefic.org/Templates/shwStory.asp?NID=494&HID=645&PHID=643&PPHID=494>

➤ **ECHA Guidance on SIEF:**

[http://echa.europa.eu/sief\\_en.asp](http://echa.europa.eu/sief_en.asp)

➤ **ECHA Guidance on data sharing:**

[http://reach.jrc.it/docs/guidance\\_document/data\\_sharing\\_en.pdf](http://reach.jrc.it/docs/guidance_document/data_sharing_en.pdf)

➤ **Business rules:**

[http://echa.europa.eu/doc/reachit/reachit\\_data\\_submission\\_manual\\_8\\_business\\_rules\\_validation\\_20090417.pdf](http://echa.europa.eu/doc/reachit/reachit_data_submission_manual_8_business_rules_validation_20090417.pdf)

## End of the presentation



**Thank you for your attention!**