



**SIEF Workshop**  
**30/03/09**



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# Agenda

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## Introduction

- Framework (Commission)
- Statistics (ECHA)
- Presentations industry

## Discussion topics

- Set-up SIEF
- Substance identity
- Dossier submission

## Round-up

How to communicate this?

# Agenda

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## Discussion topics

- **Set-up SIEF**
  - SFF – LR
  - Multiple LR
- **Substance identity**
  - Split/merge/change
- **Dossier submission**
  - Timing
  - Opt-out
  - Early registrations and joint submission

# Set-up SIEF

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## SIEF and SFF

- Feedback industry surveys

# Set-up SIEF

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## Cefic survey

- **28 Companies approached**
- **16 replies**
  - **Total pre-registrations: 34.841**
  - **Total substances: 9.714**
  - **For 1010 deadline: 1.355**
  - **Having SFF/LR: 1.012**

# Set-up SIEF

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## What if no SFF?

- Only pre-registered to be on safe side?
- Everyone thinking some one else will do it
- How to find those that will/must result in registration?

# Set-up SIEF

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## SFF

- Companies
- Service providers

## What to do if nothing happens?

- No reaction
- Blocking the work
- *How to handle this?*

# Set-up SIEF

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**SFF is not by definition the LR**

**SIEF status 4 coding**

- **Leading, logically LR should come from this group**
- **Involved**
- **Passive**
- **Dormant**

**Timing**

# Set-up SIEF

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**LR advised to inform ECHA**

**What with multiple LR?**

- **Multiple consortia possible for the same substance**
  - **EU vs non EU**
  - **Differences in purity**

# Substance identity

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## Merging/splitting/changing

### How will this work in practice?

- Number, name?
- Is the read-across substances enough as possibility?

# Substance identity

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ECHA proposes a process using the read-across to access other pre-SIEFs but:

- ❌ No possibility to download XML with contacts
- ❌ Companies from the new pre-SIEF have no way to see the newcomer who wishes to join
- ❌ It is therefore up to the newcomer to pro-actively contact (manually one-by-one) the members of the new pre-SIEF

# Substance identity

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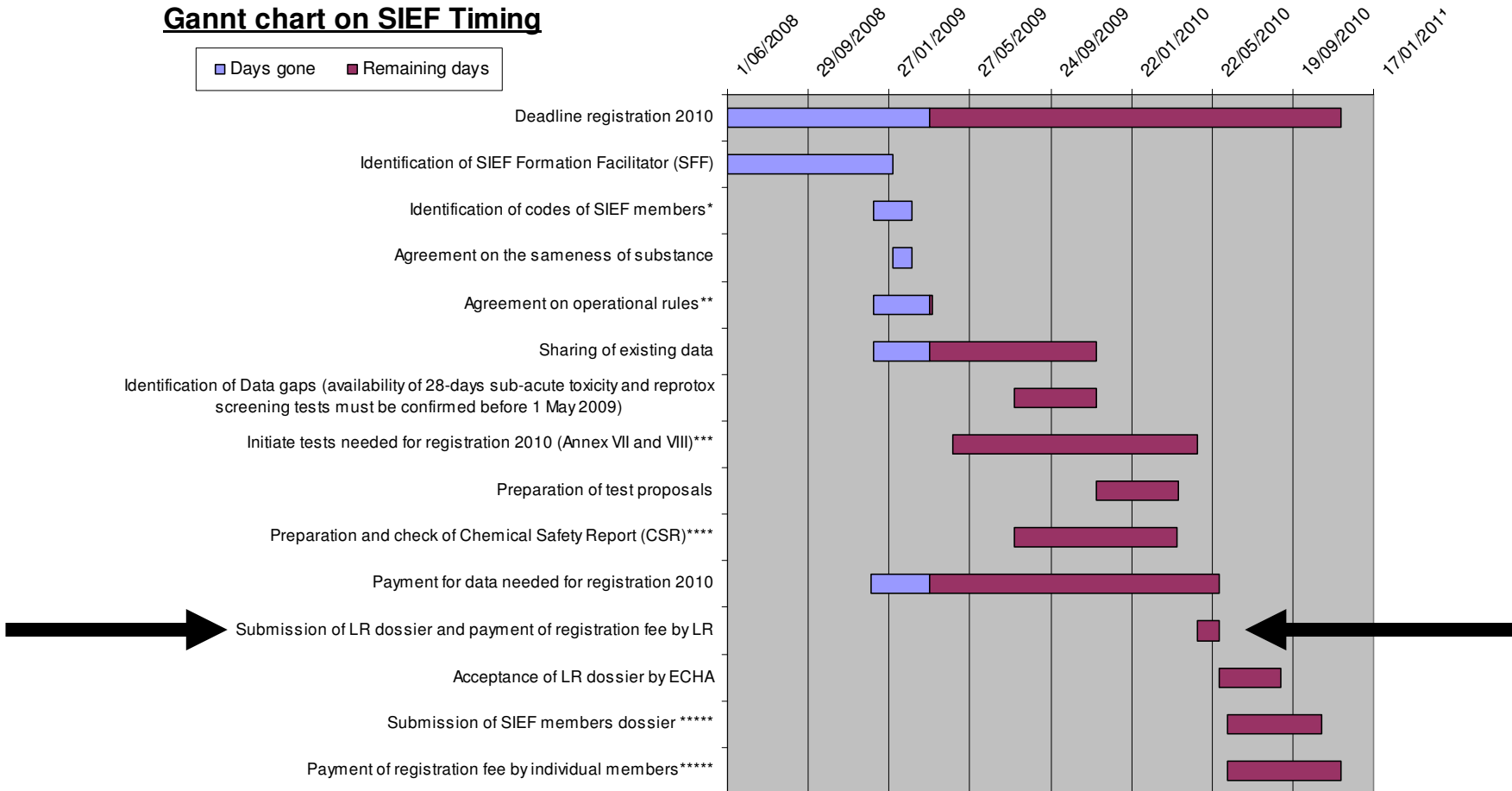
Questions:

- ✓ Is there a more practical way to change pre-SIEF?
- ✓ Can companies join a different pre-SIEF using a similar process as for Data holders?
- ✓ Can REACH-IT show the newcomer and include him in the XML download?

# Dossier submission



**Gantt chart on SIEF Timing**



# Dossier submission

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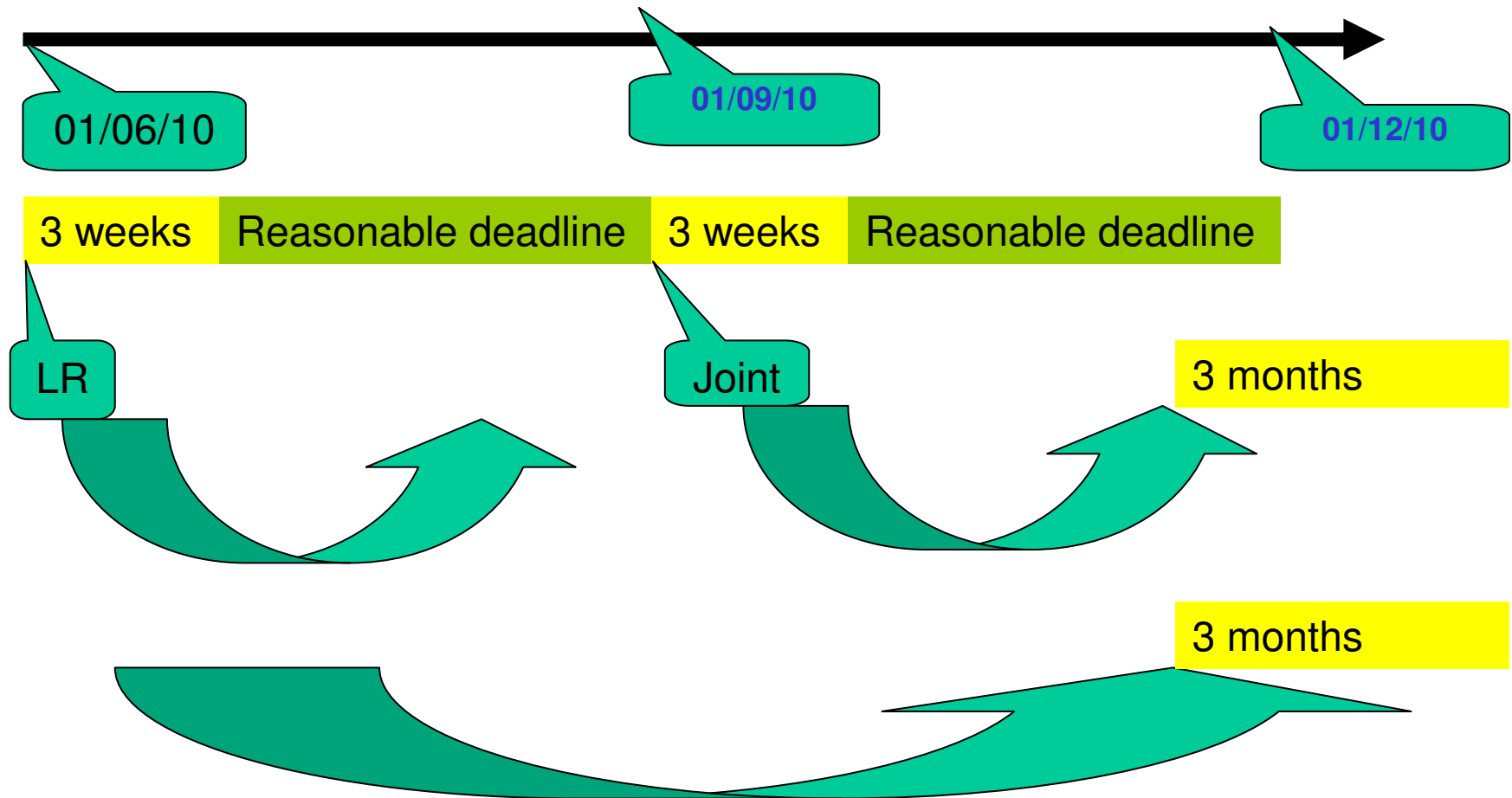


## Art 20 § 2

- ...The Agency shall undertake the completeness check **within three weeks of the submission date, or within three months of the relevant deadline of Article 23**, as regards registrations of phase-in substances submitted in the course of the two-month period immediately preceding that deadline.

If a registration is incomplete, the Agency shall inform the registrant, before expiry of the three-week or three-month period referred to in the second subparagraph, as to what further information is required in order for the registration to be complete, **while setting a reasonable deadline for this**. The registrant shall complete his registration and submit it to the Agency within the deadline set. The Agency shall confirm the submission date of the further information to the registrant. The Agency shall perform a further completeness check, considering the further information submitted.

# Dossier submission



# Dossier submission



**(a) a technical dossier including:**

- (i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;
- (ii) the identity of the substance as specified in section 2 of Annex VI;
- (iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;
- (iv) the classification and labelling of the substance as specified in section 4 of Annex VI;
- (v) *guidance on safe use of the substance as specified in Section 5 of Annex VI;*
- (vi) study summaries of the information derived from the application of Annexes VII to XI;
- (vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;
- (viii) an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;
- (ix) proposals for testing where listed in Annexes IX and X;
- (x) for substances in quantities of 1 to 10 tonnes, exposure information as specified in section 6 of Annex VI;
- (xi) a request as to which of the information in Article 119 (2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

**(b) a chemical safety report when required under Article 14, in the format specified in Annex I. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.**

# Dossier submission

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## Art 11

- 3. A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:
  - (a) it would be disproportionately costly for him to submit this information jointly; or **(total opt-out?)**
  - (b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or **(partial opt-out)**
  - (c) he disagrees with the lead registrant on the selection of this information. **(partial opt-out)**

*How in practice?*

# Dossier submission

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## Early registrations and joint submissions

- **Some companies send in their registration for phase-in substances**
- **Seen the phase-in status no inquiry needed**
  - **How will this be handled?**