

Registration 2013: Experiences and lessons learned

Agenda

- Overview of Eastman's 2010 REACH status
- Looking back to SIEF challenges 2010
- Expected challenges for 2013
- How to prepare as a LR?
- Cost sharing
- Post registration challenges in SIEFs

Eastman Chemical's REACH Dimensions

2010 REACH registrations	53
2010 Substances	44
Lead Registrant	17
Consortia	7
Involved status SIEFs/Consortia	24
2013 - 2018	"164"

2010 Challenges going from pre-SIEF to SIEF

Issue	Solution
➤ Difficult SFF	➤ Recommendation to bypass
➤ Large numbers of SIEFs	➤ Coding system (1-4)
➤ No SIEF communication systems	➤ From e-mail to specific tools
➤ LR liabilities	➤ SIEF agreement
➤ Survey	➤ SIEF Management tools
▪ Registration intention	➤ Clear, transparent and regular communication
▪ Sameness	➤ Use industry standards
▪ Data availability	
▪ LR vote	
▪ C & L	

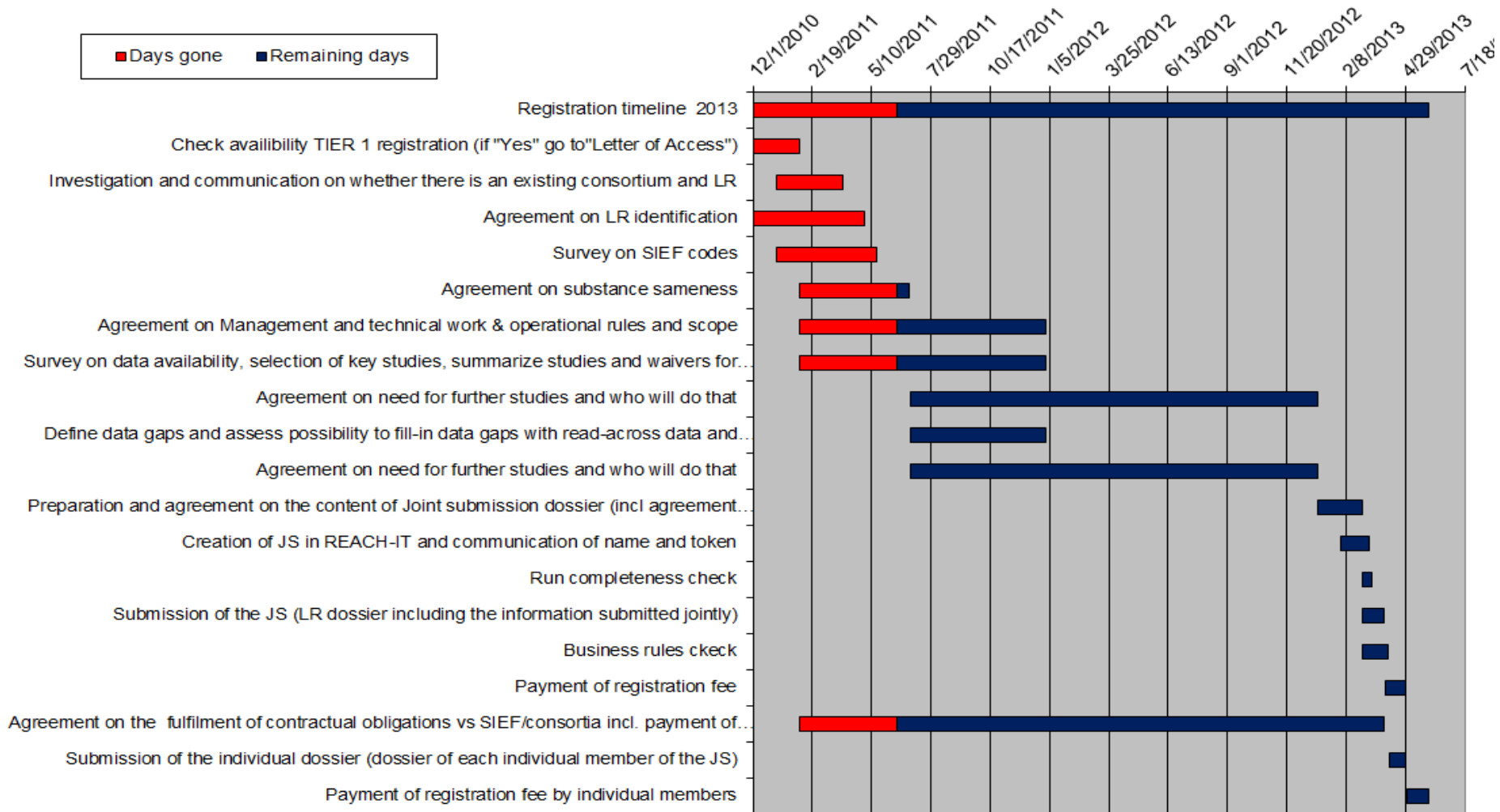
New challenges for 2013 deadline

- More substances, smaller SIEFs
 - Specialty chemicals, lower number of registrations per substance
- Less substances covered by consortia or SLT's
 - No more HPV bulk chemicals/substances
 - More SIEFs run by just the LR
- Less data available
 - Limited lab capacity to run 28 day toxicity tests
 - Scientific support for alternative test methods required
 - More Annex IX test proposals

New challenges for 2013 deadline cont'd

- Less experienced LR's
 - Less resources, knowledge
 - Limited number of experienced consultants available
 - Project management Gantt chart on Cefic web site
- More SME's will need registrations
 - Focus on cost of LoA's
 - Transparency in cost structure and content

Project Management Sheet



Preparation of documents by LR

- Use older version of MS Office, or send in pdf format
- Substance Identity Profile (SIP)
 - Template on Cefic website
- Agreements
 - SLT/consortium agreement if applicable
 - SIEF agreement including LoA
 - Be clear on CSR i.e. jointly prepared/submitted or not
 - Model agreements on Cefic web site
 - Cover letter to SIEF agreement re cost structure
 - Include potential additional cost for work after registration e.g. executing test proposals, evaluation etc.
 - As a service to the SIEF members highlight where you deviate from model agreement or where you select an option

How to communicate

- Communication is key!
- Make use of web based SIEF management tool
 - Substance specific site with information on SIP, C&L, survey information, LR identity etc
- Download XML file for EACH round of emails
- Keep all emails on undeliverable messages in file
- In general: No reaction means agreement with LR proposals

1st email to entire pre-SIEF; timing NOW

- Introduction of Candidate LR
- Proposed SIP attached
 - Template on Cefic web site
- Registration intent survey (SIEF codes)
- Intermediate/full dossier required
- LR vote
- Call for ALL available data; not just vertebrate animal data

2nd email to entire SIEF, timing Q2/2011

- Inform that results of survey are posted on SIEF management tool website
- If applicable inform SIEF that progress can be checked on LR's web site (recommended)
- Confirmation of LR → Notify ECHA

3rd email to entire SIEF

- After hazard assessment:
 - Propose C&L by asking for agreement by ticking box on survey
 - Posting C&L on tool and LR web site

4th email to LE's interested in 2013 registration; timing 2012

■ Cover letter to SIEF agreement

- Explain cost structure: Reimbursement system vs fixed price for LoA
- Information to be provided upon payment of the LoA
 - IUCLID export file
 - JS name
 - Token
 - CSR e.g. for most common uses

■ SIEF agreement

- Which uses will be covered in the CSR
- Accepting means agreement with the SIP

Example of Eastman's website with SIEF information





2,2,4-Trimethyl-1,3-pentanediol Monoisobutyrate

Eastman will be the Lead Registrant for this substance as outlined in the REACH requirements.

Chemical Name: 2,2,4-trimethyl-1,3-pentanediol monoisobutyrate
Abbreviation: Texanol
CAS#: 25265-77-4
EC Number: 246-771-9
Contact: sub.25265-77-4@eastman.com

Additional Documents

-  [Substance Identification Profile](#)
-  [Product End-Uses](#)
-  [Pre-SIEF Communication](#)
-  [Classification and Labeling](#)

Dossier Preparation Status     **Completed**

Key Steps in preparing the Registration	Status	Remarks
SIEF leadership team available	Yes	Eastman, Dow, Perstorp
SIEF agreement available	Yes	
End-uses defined	Yes	
Classification & Labeling proposal available	Yes	View Document
CSA/CSR to be prepared and submitted	See Comment**	Hazard assessment only
Exposure Scenarios available	n/a*	Not classified
Dossier type	Full dossier	Registration completed by LR
Registration Token available	Yes	Mid - July 2010

*n/a = not applicable

**Comment: Please note the following: Eastman, as a Lead registrant, will NOT submit a joint CSR on behalf of the co-registrants of this SIEF. Instead, Eastman will make sections B3-8 of the CSR available for all co-registrants.

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Cost sharing

Key words are **transparency** and **fairness**:

- Explanation of cost sharing system e.g. cover letter
- Pay for the data you need (tonnage band, intermediate...)
- Administrative costs may include:
 - SIEF management
 - Preparation of IUCLID dossier, RSS, CSR
 - Generation of invoices, letters of access, etc.
 - Provision for reimbursement (with a threshold?)

Cefic published notes on transparency and fair cost sharing

Challenges post registration

- Regular and systematic monitoring of compliance
 - Implementation of RMM
 - Volume tracking
 - SVHC updates
- Update of dossiers:
 - Outcome of testing proposals, compliance check
 - Check your REACH-IT in-boxes
 - New guidance
 - New uses