

REACH Lead Registrants Workshop

**How to Manage a SIEF with 1000's Members :
Making Best Use of Consortia within SIEFs**

11th September 2009

Lower Olefins and Aromatics (LOA) Consortium

Scope

Olefins : Ethylene, Propylene, Butadiene

Aromatics : Benzene, Toluene, Xylenes, Cyclohexane

Streams : from steam cracking and aromatic units

- **136 Substances**
 - 30 substance dossiers
 - 106 substances benefit from category approach in 14 categories

SIEF Management and Strategy

- **Thoughts early / mid 2008**

- **Actions**

- Cooperative collaboration
 - Study review
 - Expert sessions
 - Classification and Labelling

- **Tools**

- Discussion fora – chat rooms
 - Email communications

- **Major issue - how to get adequate company representation with available resource with many SIEFs to monitor.**



- **January 2009 reality**

- **Many more pre-registrants than anticipated > x10**

- Makes communication difficult
 - Meaningful dialogue almost impossible
 - Individual company voice diluted

- **Needs strong action to drive process**

- **Consortia to fill leadership void**

- With common wider industry interest
 - Take costs on as part of overall REACH costs
 - Leverage Member company efforts

- **Major issue - how to communicate be**

- Fair, Transparent and non-discriminatory



SIEF Engagement Within LOA

- **Objectives**

- Provide REACH compliant, cost-effective representation
 - One manager/contact point responding to the SIEF rather than many representatives from the Consortium membership.
- Provide central platform for
 - Data rights management
 - SIEF engagement and management
- Provide consistency of action between all the substances in which the Consortium has an interest.
- Provide a single mechanism for SIEF members to enter proprietary data into a number of SIEFs
- Facilitate common positions on classification and labelling
- Ensure that non-animal approaches between relevant substances are used to the full - e.g. Categories
- Consistent mechanisms on
 - Letter of Access
 - Lead company
 - Billing mechanisms

LOA SIEF management

- **Phase 1 - Introduction**
 - ✓ E-mail each SIEF participant for every substance to:
 - ✓ Offer the Leadership of the Consortium
 - ✓ Intentions and deliverables
 - ✓ Technical plans , Timelines, Indicative potential costs,
 - ✓ Request early buy in to processes
 - ✓ Present Options
- **Phase 2 – Communicate and Publish**
 - ✓ SIEF surveys on intentions - publish online
 - ✓ Derive and publish Letter of Access costs
 - ✓ Propose / Publish Lead Company
 - ✓ Sameness
 - C&L
 - Availability of dossiers
 - Terms and conditions
 - Contracts
- **Phase 3 - Dissemination**
 - Token, Dossier, guides

SIEF Communications

- Keep it simple – SIEF has low level of knowledge
- Response rate - 10 to 25%
- 10% of pre-registrants likely to register
 - Spread over 2010 to 2018
- Published in LOA SIEF pages



Web Results System - LOA REACH Consortium

acetylene SIEF

This report contains data submitted up until 01/04/2009

CAS Number: 74-86-2

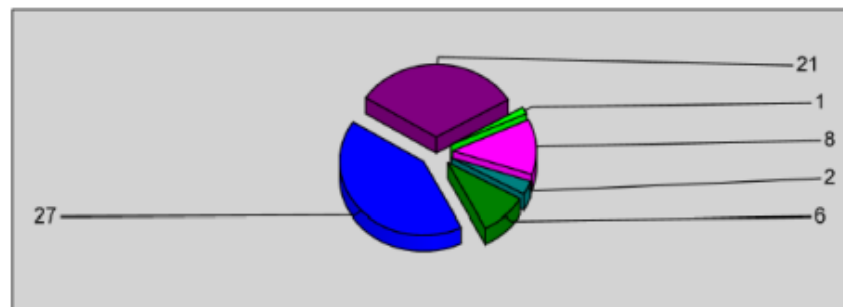
EC Number: 200-816-9

These are the results from the SIEF Intentions Online Questionnaire for:

acetylene

Timing of Registration

Pre-Registrants were asked to indicate when they would register this substance:



Type of Registration

SIEF Report

acetylene
EC No. (200-816-9) CAS No. (74-86-2)

LOA REACH Consortium
Tervuren Belgium

Close Edit

Welcome Sameness Disc. Proprietary Data Survey Results Class. & Labelling Uses & Exposure Dossier Avail.

Welcome to the LOA REACH Consortium's SIEF Pages

Welcome SIEF Member

The **LOA REACH Consortium** (Lower Olefins and Aromatics REACH Consortium) was set up in June 2008 and the current membership constitutes the vast majority of the EU manufacturing capacity for the substances covered by the Consortium.

A detailed list of substances covered by the Consortium and further information about us can be found on the **LOA REACH Consortium** website (www.loa-reach.com) including regular progress updates.

We seek to operate in a fair transparent and non-discriminatory way and are open to new members.

All information pertaining to the management of this specific SIEF throughout the SIEF process will be collected within these 7 tabs.

This information is managed and regularly updated by the LOA SIEF Manager Helen Penman.
Please contact me at the email address below if you have any queries.

sief.manager@loa-reach.com

This is a dedicated SIEF page for 'Acetylene', CAS Number: **74-86-2**.

The proposed **Lead Registrant** for this substance is **SABIC Petrochemicals BV**.

If you have any comments, please contact us before May 15th 2009.

COSTS

The proposed cost for a Letter of Access for Acetylene (EC Number: 200-816-9) is **5000** euros for the full dossier and **2500** euros for the intermediate dossier. Please read the Letter from the LOA Chairman for more details.

Available Documents Common to all LOA Substances)

Filename	Description	Attachment Type
Welcome Letter From LOA Chairman.pdf	Sent: 13/01/2009 - Welcome to the LOA REACH Consortium from Chairman of the LOA General Assembly.	General Attachment
LOA Activities Overview.pdf	Sent: 01/11/2008 - A presentation of the initial activities of the LOA REACH Consortium.	General Attachment
LOA 1st Email.pdf	Sent: 14/01/2009 - Introductory Letter from the LOA REACH Services Team SIEF Manager.	General Attachment
LOA 2nd Email.pdf	Sent: 03/02/2009- Further basic information on the LOA REACH Consortium.	General Attachment
LOA Online Survey Request.pdf	Sent: 13/02/09 - Letter requesting users to complete the initial online survey, SIEF Intentions.	General Attachment
LOA REACH SIEF Communication on LOA Cost May 2009 .pdf	Sent: 19/06/09 - LOA Costs Communication from the Chairman of the LOA General Assembly	General Attachment

Available Documents for this Specific SIEF Only

Available Documents

No Attachments



Registrant Workshop
September 2009

Identification of LOA Lead Registrants

- 1. Proposal made and agreed within the Consortium based upon**
 - Proportional share of effort
 - Involvement in the technical work
 - Substance versus Intermediate registration
 - Tonnage
- 2. Proposal published on SIEF information page**
 - Letter to inform all SIEF members - request for comments or alternative proposals within limited time (2-3 weeks)
- 3. If no disagreement (none) - notified to ECHA (May)**
 - Have now filled in the ECHA web form for all LOA substances
- 4. Legal entities to claim lead registrant status and token within reach IT system**


Lead Registrant - Contractual


- **Most LOA SIEFs too large for LR/CoR contractual model**
 - Large number of SIEF members, large transactional costs
 - LR/LOA member company would have 1000's of contracts to administer
 - Significant rate limiting step
- **LOA centralised approach**
 - **Lead Registrant is Consortium member**
 - Contractual relationship with LOA members and Consortium Service organisation
 - Many activities to be centralised for all substances in a 'bespoke' IT solution
 - Provides single point of contact for LOA SIEFs
 - **For Co-registrants not in LOA**
 - Standard Terms and conditions for access to LOA output (based around CEFIC Model Agreement)
 - Online distribution and signature
 - Proactive and transparent communication with SIEF members

What will LOA Provide to Members and Co-registrants who pay for Letter of Access?




1. Substance ID,
Composition, analytical

2. Classification and Labelling 

3. Manufacture, use, exposure 

13 – CSR Part A + specific aspects

2. Classification and Labelling 


4. Phys chem properties


5. Environmental fate

6. Ecotox

7. Guidance on safe use

:

13. Assessment reports
CSR Part B 

Common elements of the extended
Safety Data Sheet 

- Exposure Scenarios

Every Registrant
Company data
LOA Guide

Lead Company
submits
Co-registrants refer
SUBJECT TO INTERESTS OF MEMBERS (intermediate vs. substance) AND DATA RIGHTS ACQUIRED BY LOA

Every Registrant
SDS or communication


Lead Registrant Issues

- **Concerns being expressed on taking on LR role**
 - No clarity on the anticipated level of commitment /Liability
 - No clear business process or timeline
 - Expectations / workload ??
 - Consequence - hard to make the business case to take the lead
 - Concerns reinforced by current high rejection rates of submitted dossiers and ‘changing expectations’
 - Lack of clarity of rationale for ‘failure’; changing Guidance; lack of early availability of CTT/ECHA ‘rules’
- **External consultants – muddied process**
 - Who could be trusted to deliver? Would they block legitimate interests?

Questions P

Back-Ups

LOA SIEF management

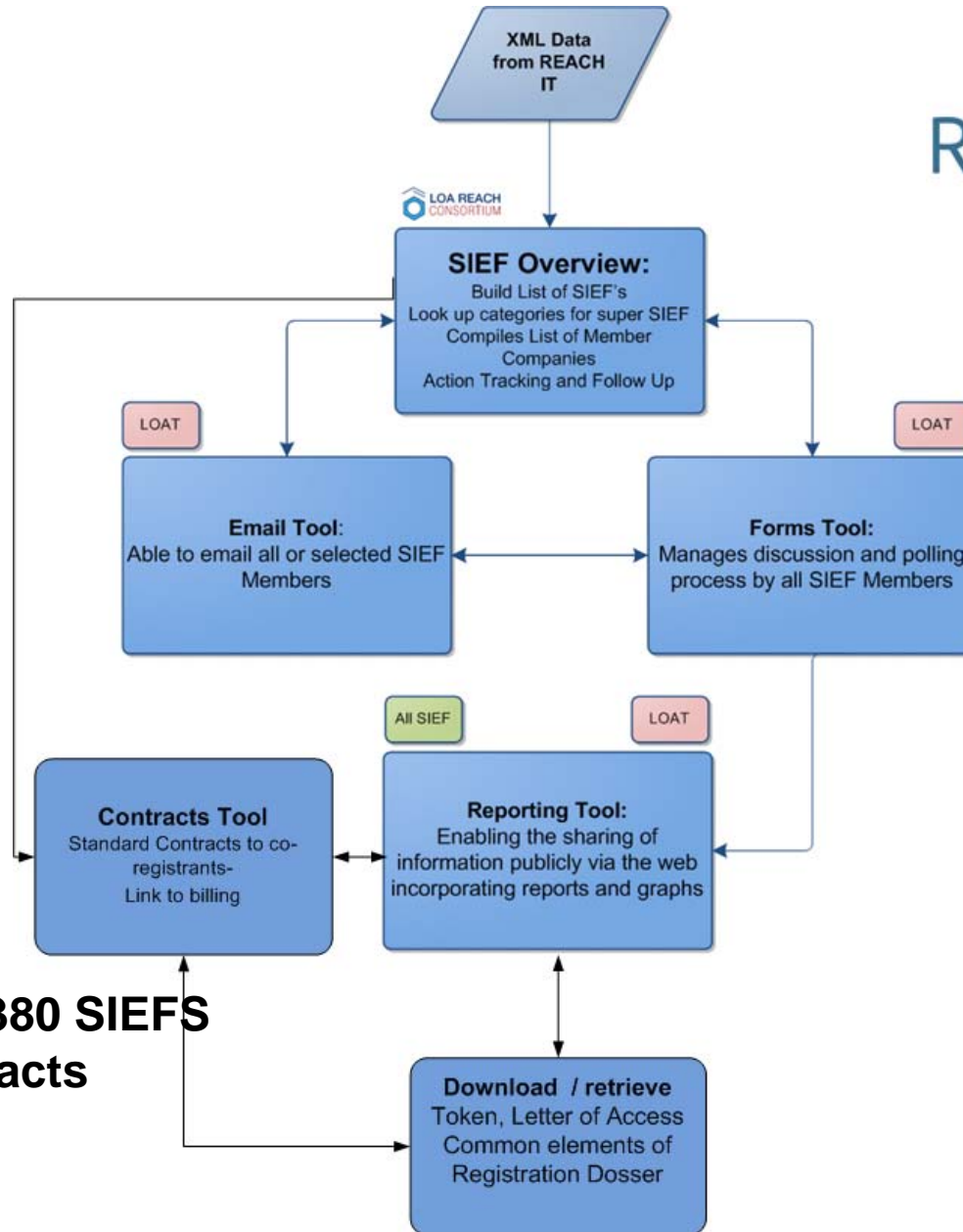
- **Scope for LOA - 130 SIEFs, 37,000 initial contacts**
 - Large number of high volume SIEF members (>1000)
- **LOA TA nominated as TPR by Members companies in order to manage / download data etc.**
- **Costs taken by Consortium – No charges to any SIEF members**
 - Ensures transparency of action and wide engagement across the SIEF
 - Recovery through Letters of Access (very small cost as compared to other technical and operational costs)
- **Tool used – integrates with all other Consortium management activities**
 - Substances, Companies, Services providers, Intentions, Costs, Uses / Exposure, Data storage, Action tracking, progress metrics
- **No Legal Entity deactivated in the management system unless requested** 
 - Ensuring all information go to all SIEF participants at all times
- **SIEF Members update their core details in REACH IT – not in LOA system**
- **Weekly downloads of SIEF files to keep LOA databases current and synchronous with ECHA**
 - Significant number of additions
- **Minimal email traffic possible – some is inevitable**
 - Still a considerable time responding to questions / requests
- **Extensive use of forms technology to gather data**
- **Manage both as substances and in categories**
- **One FTE manages activities SIEF.Manager@LOA-REACH.com**

Costs of Letters of Access published

- **Costs of Letter of Access determined by**
 1. **Analysis of how each information requirement will be met**
 1. **Data gap analysis for each substance/category**
 2. **Understanding which studies will provide key and support information**
 3. **Understanding which studies are proprietary and due compensation in line with Consortium rules**
 4. **Information stored in management system costs allocated**
 2. **SIEF survey on likely number of registrants at the tonnage band's**
 3. **Integration of 1 and 2 using 2010 registrant intentions**
 - **Principle of equality across consortia and SIEF members**
 4. **Each substance placed into a band**
 5. **Offer prices of €5000, €10000 and €20000**
 6. **Prices published on the SIEF pages**

- **Major item to resolve the majority of questions on SIEF management.**
- **Subsequent questions on cost mechanism.**
- **Significant number of new committed SIEF members**
- **Increased willingness to bring forward Registration timelines**

SIEF Management Module



**In use by >380 SIEFS
70,000 contacts**



Contractual tool

- Allows standard data access contract to all SIEF members
- Legal entities and UUID added from SIEF management system
- Flexible for each contract part / Annexes / conditions / signatures
- Electronic signature
- Link to Invoicing
- Once paid - release
 - Token
 - Dossier
 - Associated documentation

