



# **SIEF-IT system**

**REACH-IT workshop – 14 April 2008**

***Jack Wille - Cefic***



## Topics:

- **Project Background**
- **SIEF-IT system overview**
- **The company (ReachLink)**
- **The future: Industry Portal**



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## SIEF IT system - Background

- The obligation to share animal study data in SIEFs (Substance Information Exchange Fora) and Submission of a Joint Registration:

### WHY

- is industry's responsibility
- the European Agency (ECHA) will not be involved
- therefore industry has to find a solution

- Cefic initiative: IT platform giving service to **all industry**, providing for:

### WHAT

- Collaboration of companies in SIEF formation & sharing of studies, identification of data gaps, cost sharing, etc.
  - Secure communication inside and between SIEFs
- Benefits for companies of a SIEF IT platform:
    - Consistent processes and procedures
    - No need for individual solutions (reducing complexity)
    - Reduced investment and lower operational cost per company

# SIEF IT system - Proposal

## HOW

- **Develop Industry wide SIEF IT system (Industry Portal):**
  - Collaboration tools (e.g. Chat box, Discussion fora, share documents)
  - SIEF Formation, Data Exchange, prepare Joint Submission
  - Secured access to information
  - Fee (low barrier for SMEs)
- **Operate and maintain IT platform:**
  - Outsourced
- **Timing:**
  - Operational by 1 June 2008 !!

**Note:** Industry Portal design will enable future additional functionality (e.g. for Supply Chain communication data)

## **HOW** Cefic Project to develop a SIEF IT system:

- Project kick-off - 31 July 2007
- Requirements Definition - 1 Oct 2007  
(by Contractor & User Project team)
- Tendering Process - 5 Dec 2007  
(for Development + Operations / Hosting)
- Decisions on: - 14 Dec 2007
  - **Business Model** (launch new company ‘ReachLink’)
  - **IT Service Provider (IBM)**
- Build phase kick-off - 8 Jan 2008
- Test version available - Apr 2008
- Operational - Jun 2008

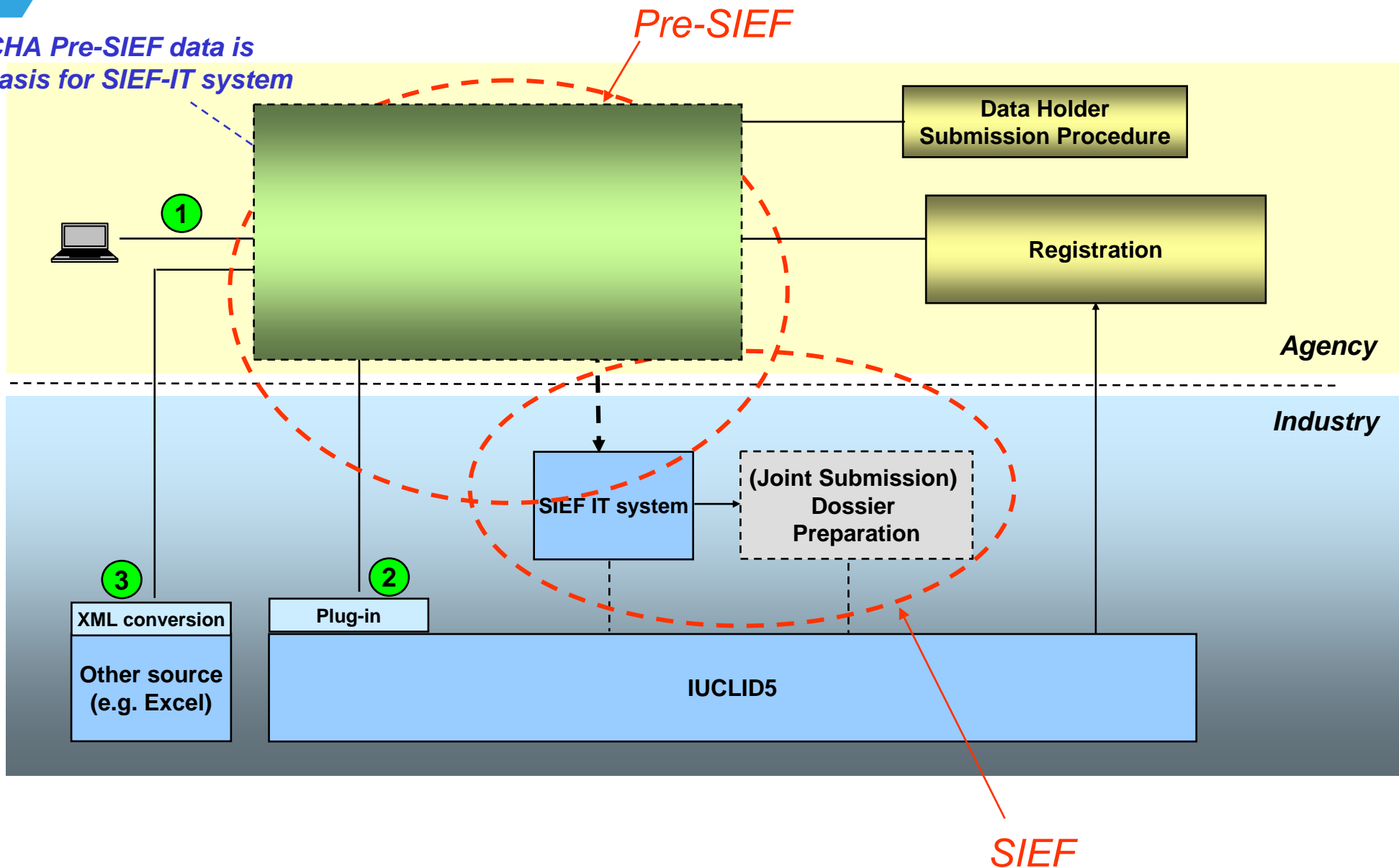
***Note: Support from majority of industry associations***

## Topics:

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- **SIEF-IT system overview**
- The company (ReachLink)
- The future: Industry Portal

# Pre-Registration / SIEF / Registration process

ECHA Pre-SIEF data is the basis for SIEF-IT system



*This slide is copied from ECHA presentation 15 Feb. 2008*

## REACH logo

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Home > [View Pre-SIEF Memberships](#) > [View Pre-SIEF](#)

Pre-registration: [Pre-SIEF](#) | [Read across details](#) | [Substance details](#)

Phase-in Information: [Pre-SIEF definition](#)

Substance: [Substance name](#)  
**phenol**

Dossier: [Caution notice](#)

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Messages

Users

Inventories

Invoices

[Information from the SIEF formation facilitator](#)  
let's meet in the CEFIC tool

[Substances to read across](#)  
[\[4-methylnonan-1-ol\]](#)

[Read from substances](#)  
[\[Reaction mass of caffeine, benzene, phenol\]](#) [\[Lactulose\]](#) [\[Reaction mass of benzene, phenol\]](#)

[Pre-SIEF partnership](#)

Select	Organisation name	Status	Info	Partnership type	Pre-Registration No.	Tonnage Band	Deadline	Contact person
<input type="radio"/>	Sand Chemicals	[F]	<a href="#">i</a>	Potential Registrant	05-2114241-76-0000	Over 1000 tonnes/year	12/1/2010	Sand Chemicals
<input type="radio"/>	Catherine's Chemical Co	[A]		Potential Registrant	05-2114190-68-0000	Between 1 to 10 tonnes/year	6/1/2018	Catherine's Chemical Co
<input type="radio"/>	John Smith	[A]		Data Holder				John Smith
<input type="radio"/>	Cather1n's Specialties	[A]		Potential Registrant	05-2114199-59-0000	Over 1000 tonnes/year	12/1/2010	Cather1n's Specialties
<input type="radio"/>	echa	[A]	<a href="#">i</a>	Potential Registrant	05-2114163-71-0000	Over 1000 tonnes/year	12/1/2010	Riitta Riala

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You may want to keep a trace of this information

- Export the full SIEF description in [PDF](#) format
- Export the full SIEF description in [XML](#) format

# Data export from Pre-SIEF (ECHA REACH-IT system) to SIEF-IT system

## ECHA REACH-IT system – Pre-SIEF

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You are connected as **Cather2n** on behalf of Catherine's Chemical Co - [Preferences](#) - [Logout](#)

Company: Home > View Pre-SIEF Memberships > View Pre-SIEF

Pre-registration: Pre-SIEF **Read across details** Substance details

Phase-in information: Pre-SIEF definition

Substance: phenol

Dossier: Caution notice

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Messages: Substance name

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Substances to read across: [\[4-methylnonan-1-ol\]](#)

Read from substances: [\[Reaction mass of caffeine, benzene, phenol\] \[bakelit\]](#) [\[Reaction mass of benzene, phenol\]](#)

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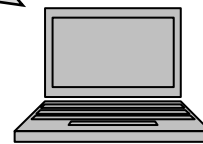
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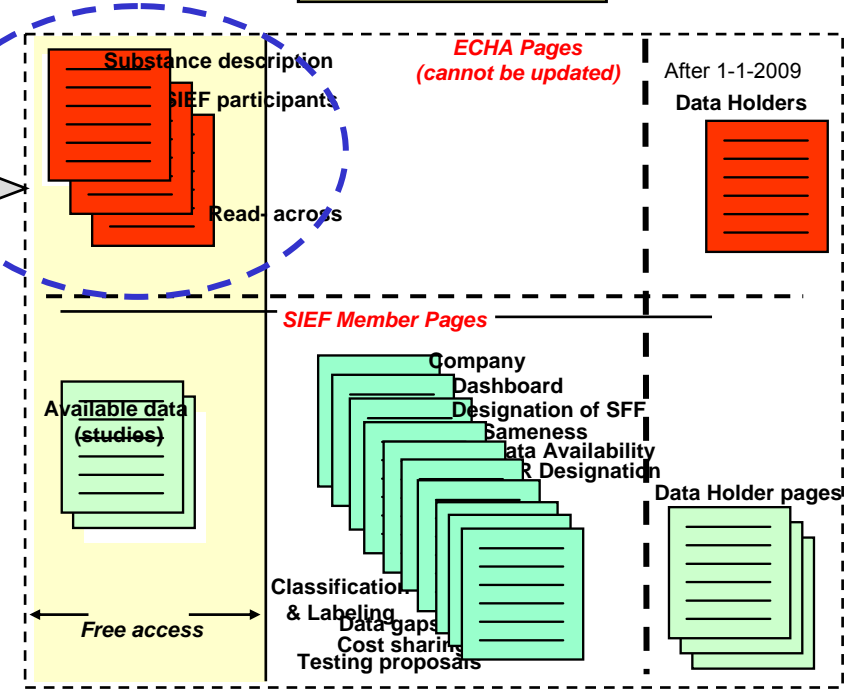
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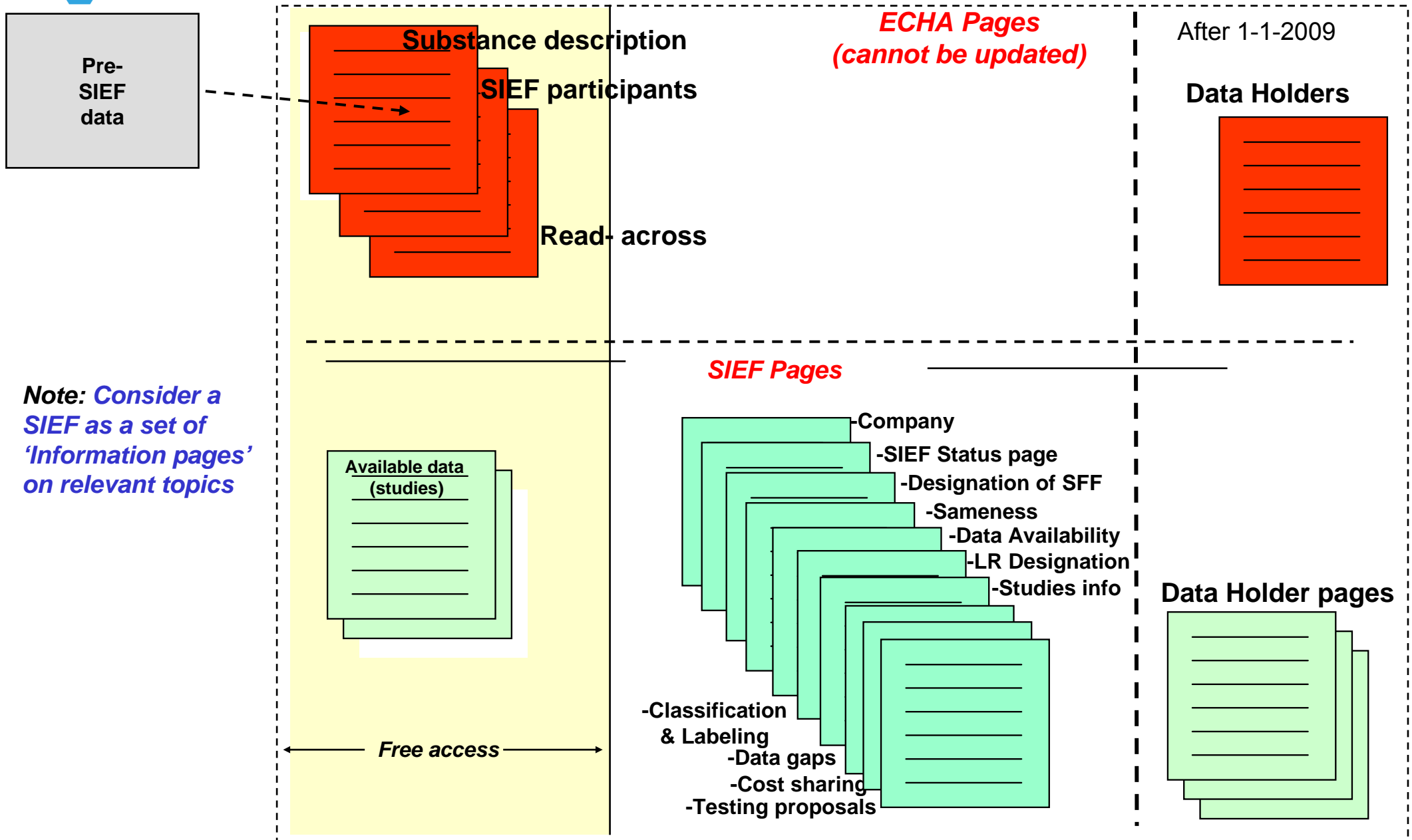
Pre-SIEF data are the basis for SIEF-IT system

Export to SIEF-IT system

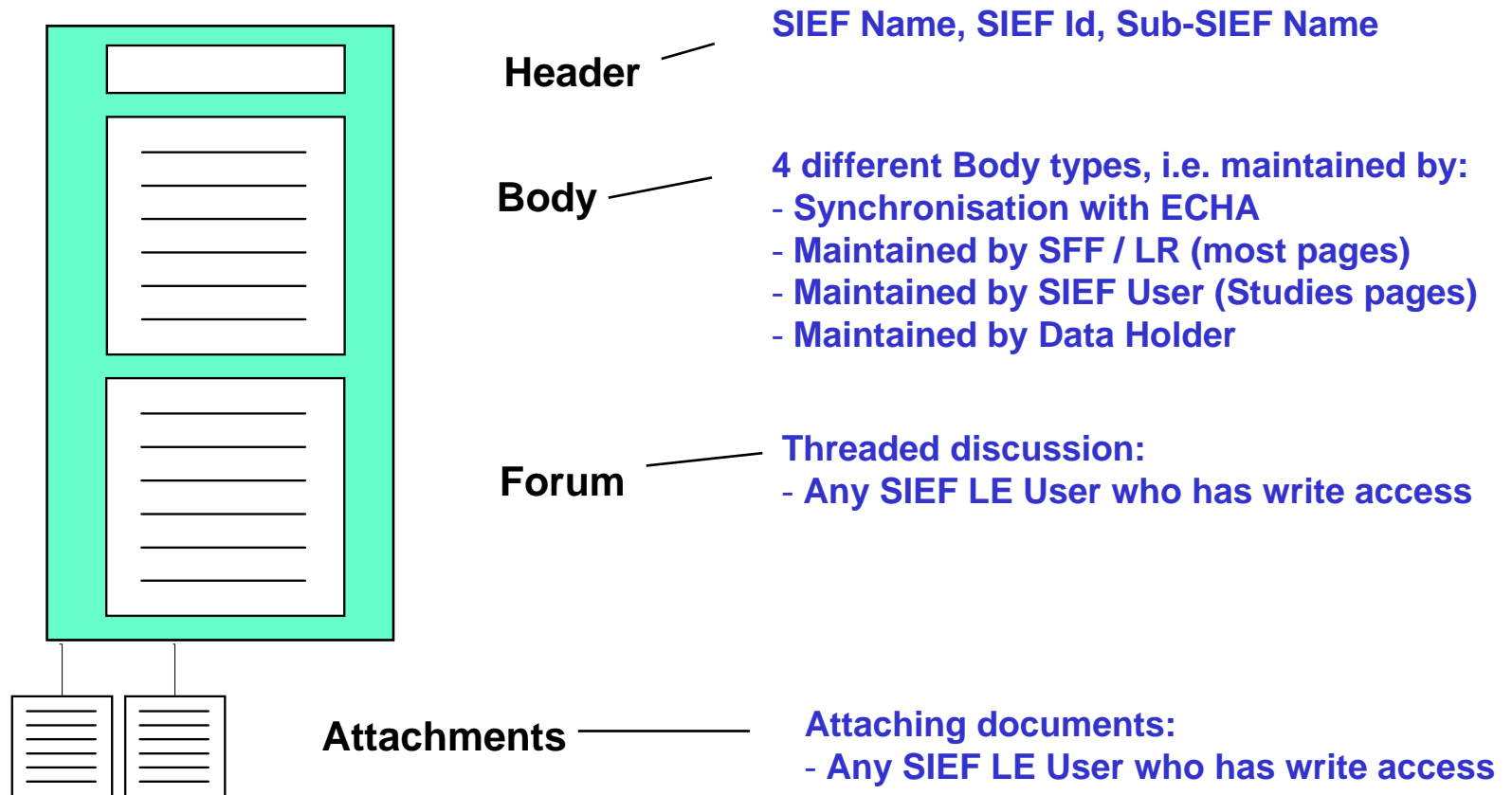


## SIEF-IT system





# SIEF Page composition



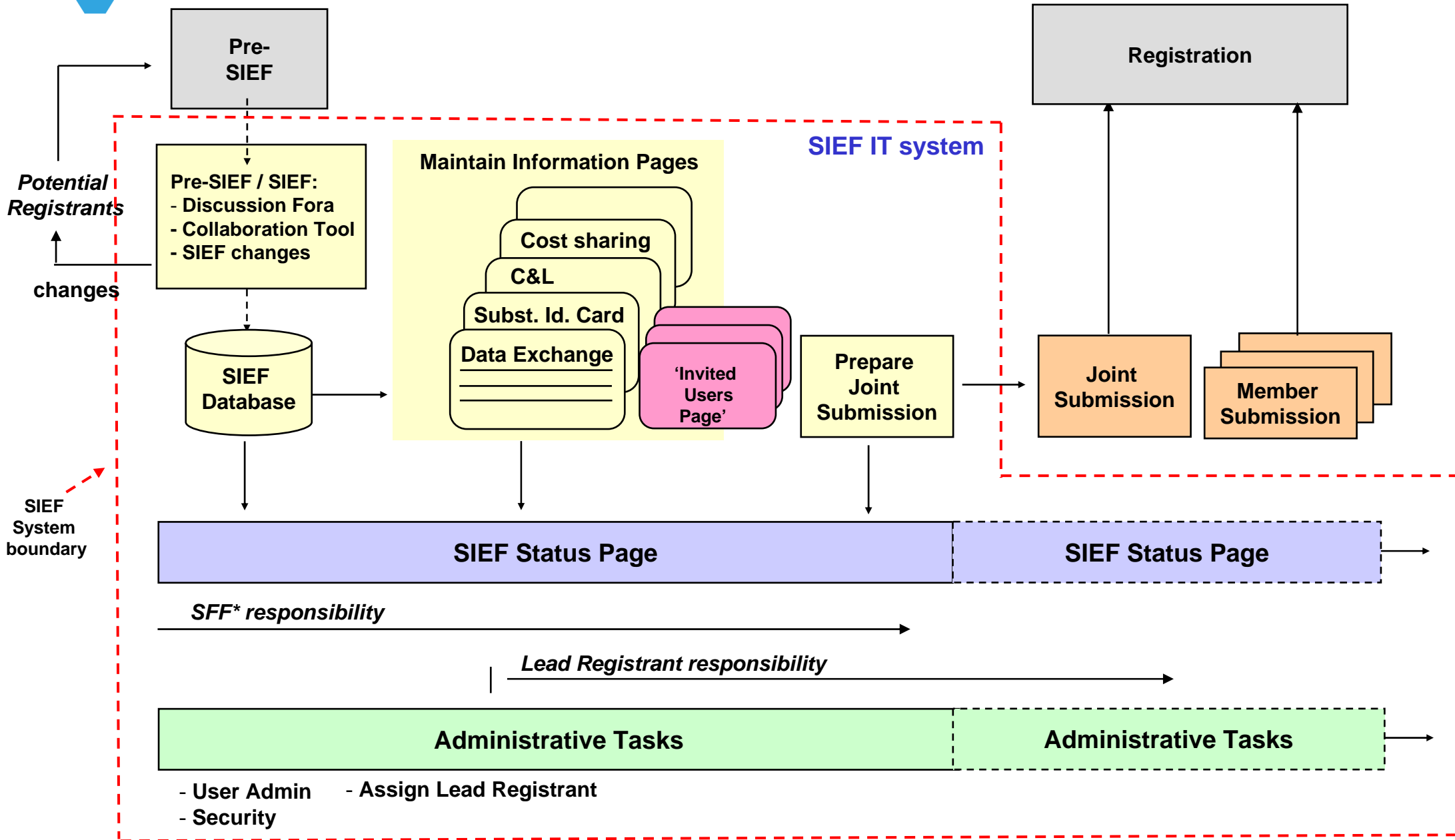
## SIEF Participant roles:

- Potential Registrant (Manufacturer, Importer or Only Representative)
- Third Party Representative (TPR)
- Registrant
- Data Holder
- Legal Entity Group Administrator
- Legal Entity SIEF User
- (External) Expert, e.g. from Lab, University, non-EU Manufacturer
- SIEF Formation Facilitator (SFF)
- Lead Registrant (LR)



From ECHA Pre-SIEF data

# SIEF IT system - Overview



\* SFF = SIEF Formation Facilitator

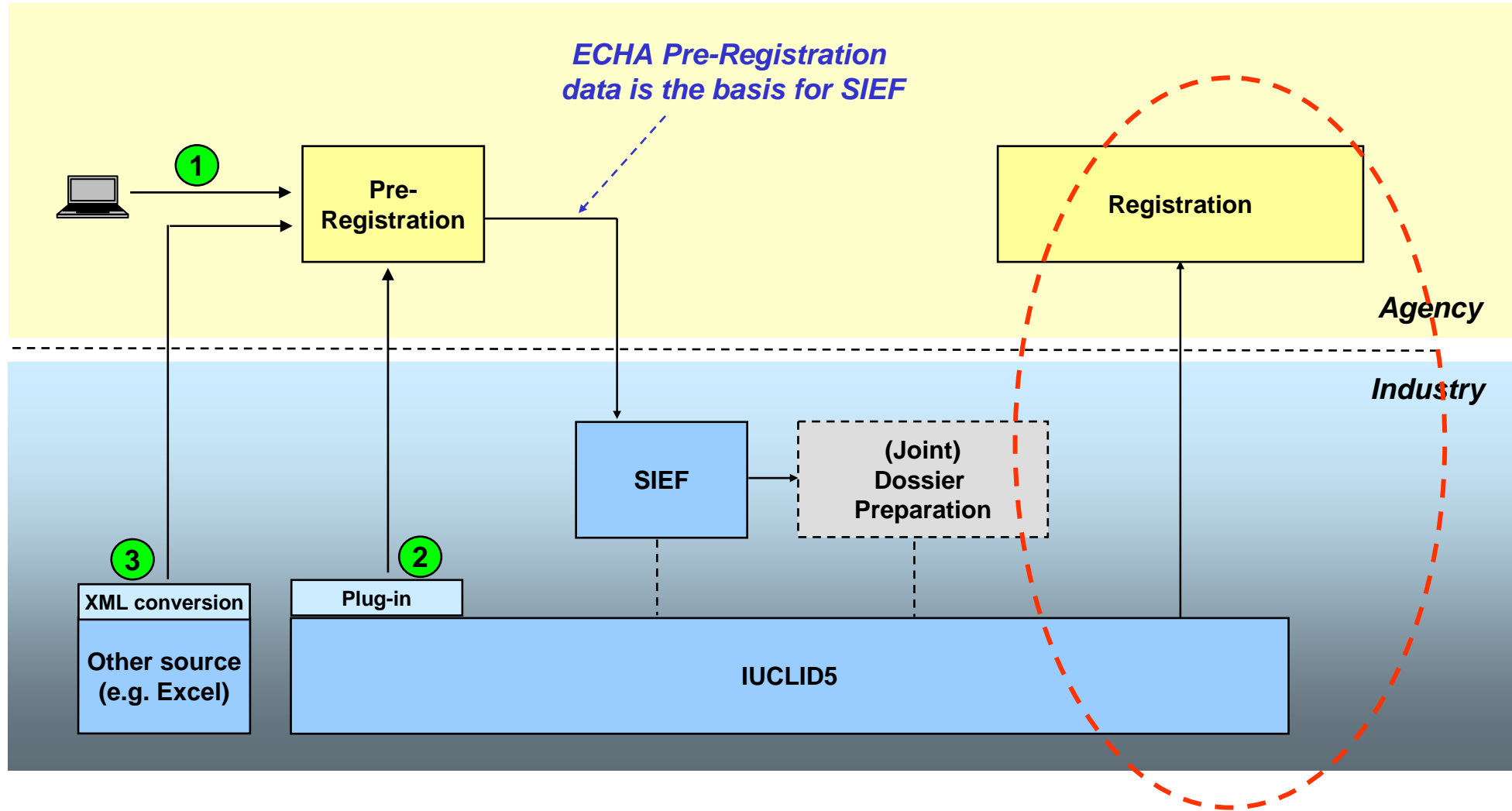
- **ECHA Pre-Registration data is the basis for SIEF formation**
- **Changes / updates will occur during / after Pre-Registration phase, e.g.**
  - Name, address, Contact person
  - Cancel Pre-registration (inactivate in system – no physical delete)
  - Late Pre-Registrant
  - Add Read-across Substances
  - Splitting / merging of SIEFs
- **SIEF activities: not a strict workflow process; However, SIEF monitoring is needed; ‘SIEF Status Page’ will be used to monitor the progress on e.g.**
  - SFF designation
  - Discussions about sameness
  - Lead Registrant designation
  - Classification & Labeling
  - List of available Studies
  - Coverage of the data gaps
  - Cost sharing calculation
  - Testing proposals
- **Synchronisation with ECHA Pre-SIEF by ‘refresh’, triggered by SIEF User**

- **Functionalities:**

- A **'free-access area'** (for active SIEF participants) with access to:
  - substance description
  - overview of the SIEF participants
  - read across functionality
  - studies available per participant (if flagged to make available)
- Pre-SIEF Sameness discussions
- Data sharing, data gaps, classification & labelling, etc.
- Support for cost sharing
- Voting and polling capabilities (nominate SFF / LR, C&L, Cost sharing method)
- 'Invited users' pages to take discussions off line within a limited group of participants, e.g. for consortia, invited experts
- 'SIEF Status Page' shows the progress on the Information Folders
- Preparation of the joint submission

ECHA Pre-SIEF data

# Pre-Registration / SIEF / Registration process



## Beyond SIEF:

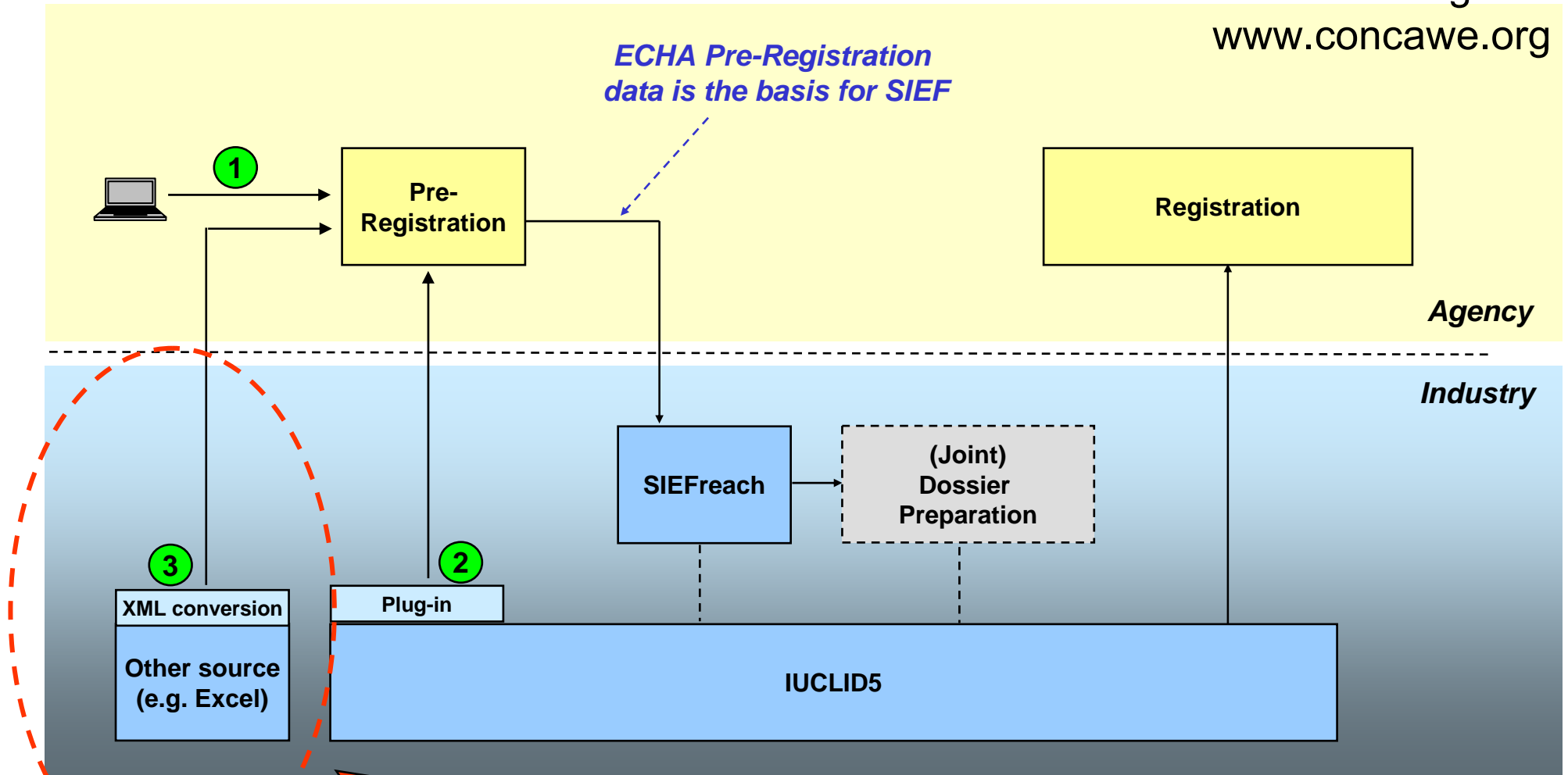
### Registration (Joint Submission):

- Lead Registrant (LR) submits Registration Dossier first
- Receives 'Joint Submission token' (ticket number)
- LR distributes JS token to other JS members
- JS members submit their registration dossier
  
- Dossiers are processed at ECHA (using REACH-IT Workflow system)

- 
- **Benefits:**
    - Streamlined transparent communication between parties
    - Consistent processes and procedures
    - Tracking of all discussions / decisions during SIEF life time
    - Designed in collaboration with major players in the Chemical Industry
    - Link with ECHA for the pre-registration data, incl. ‘refresh’ mechanism
    - No need for individual solutions (reducing complexity)
    - Lower operational cost per company
    - Controlled access & Secured communication
    - Data confidentiality (compliant to EU data privacy law)
    - Guaranteed platform till at least 2018

# Pre-Registration / SIEF / Registration process

www.cefic.org  
www.concawe.org



- Standard IT tool for bulk submission from Excel
- Developed by Concawe / Cefic
- Will be made available to companies for free (also non-members)

## Topics:

- Project Background
- SIEF-IT system overview
- **The company (ReachLink)**
- The future: Industry Portal

## **ReachLink, the SIEF Services company:**

- Company (SA) registered on 14 Jan. 2008
- Shareholders: Cefic, VCI, CIA, UIC, Federchimica, FEIQUÉ
- Ordered development of the system at IT Service Provider (IBM)
- Own / manage the system (governance)
- IT Service Provider (IBM) operates / hosts the system
- Development cost to be paid by Shareholders' financial contribution
- Operations / Hosting to be paid from fees paid by SIEF Users
- Project / Business Manager hired
- User and Steering committee established
- Marketing campaign in progress, e.g. Logo, Brochure / leaflet, ReachLink Website, Press release, Presentations and demos, CEFIC newsletters , Training

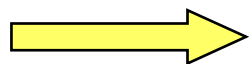
## Fee structure / payment

- Average fee:
  - 300 € per Legal Entity / Substance (one time)
- Ordering SIEF 'tickets':
  - Pre-financing (reserve SIEF-tickets now, pay < 1-Jun-2008)
  - Purchase order → Invoice → Payment → SIEF access (>3000€)
  - One SIEF ticket: Credit card payment → immediate access
- Payment mode options:
  - Credit card (instantaneous)
  - Invoice (after Purchase order)
- Discount:
  - Being finalised

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- **Focus on IT systems for REACH so far:**
  - Company level
  - ECHA systems
- **Need for industry IT layer, e.g.:**
  - SIEF IT system
  - Data standards
  - Shared documentation

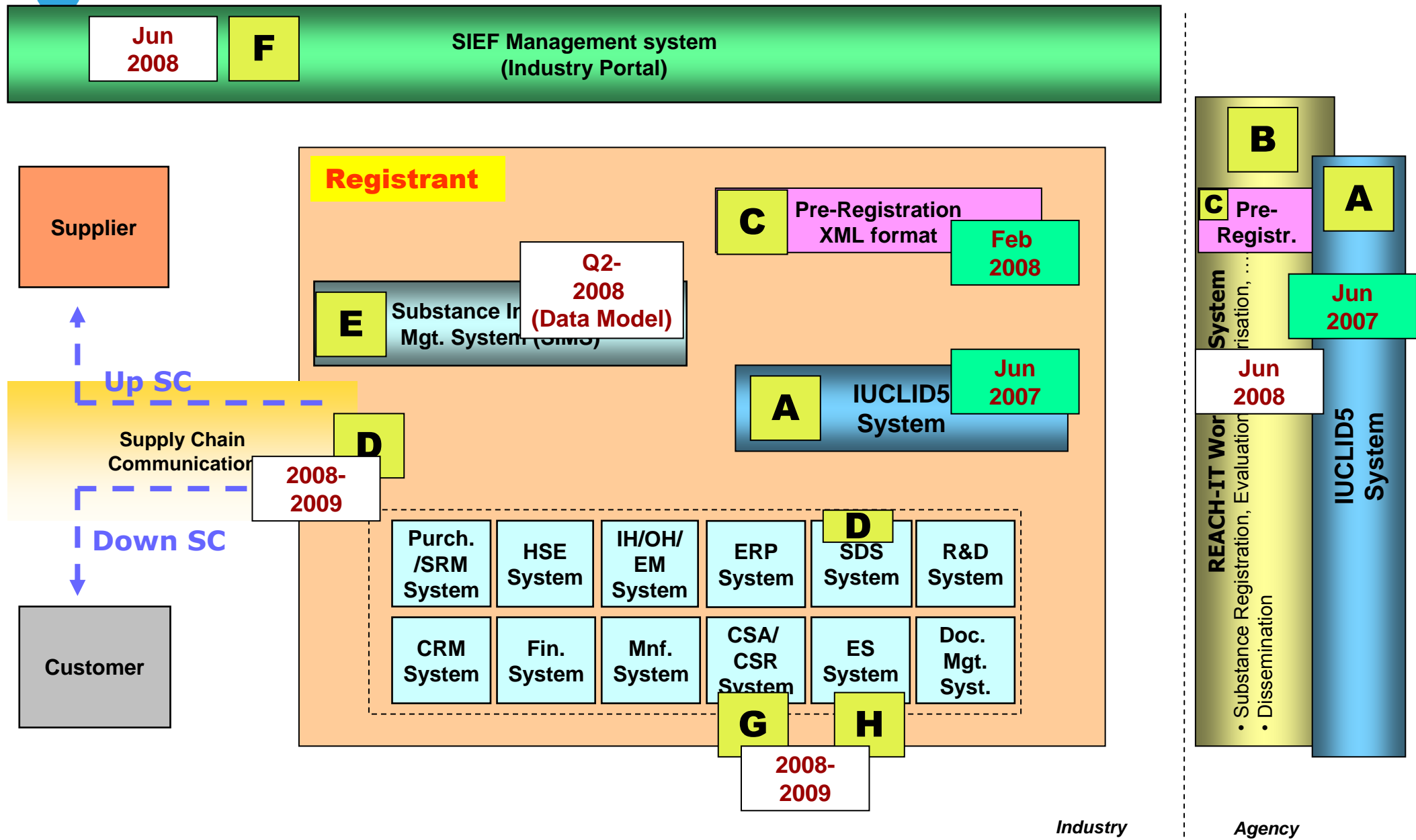


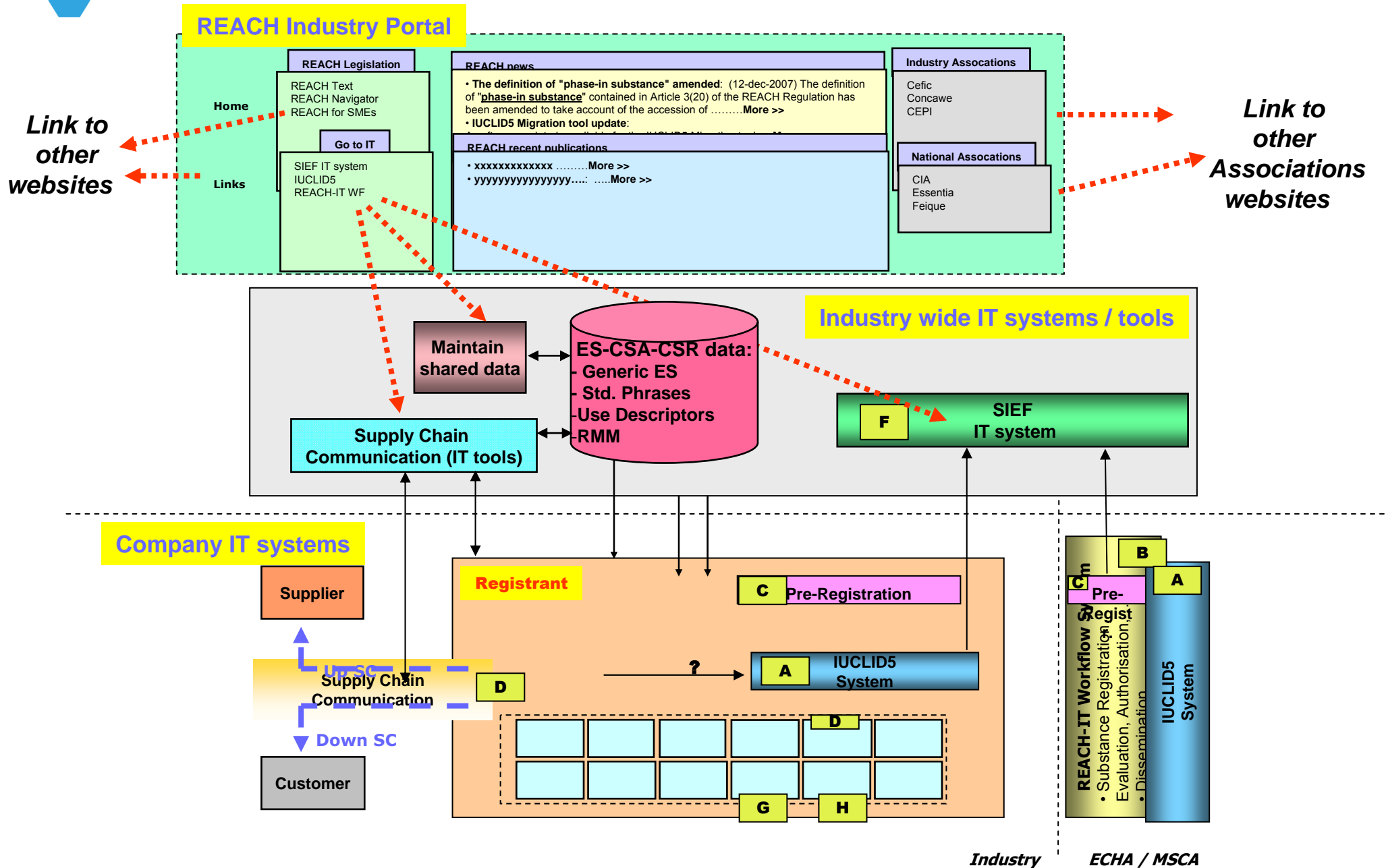
## **REACH Industry Portal:**

- Single point of access to REACH info, applications, data
- Consistent access to information, systems and tools
- Integrated security

## REACH Industry Portal – Candidate projects:

- RMM Libraries (temporary solution on Cefic website)
- Standard Phrases
- Supplier Questionnaire
- ES creation (draft → tentative → final) – replacing DU Questionnaire
- Guidance on REACH (e.g. Pre-Reg & SIEF Data Sharing)
- Access to SIEF IT system
  
- Download of common software (e.g. OECD QSAR toolbox)
- Link to other websites (REACH text, RIP guidelines)





## REACH Industry Portal – Project to be initiated:

- Basic Portal software available with SIEF-IT project
- To be defined / developed:
  - Portal scope and structure to be defined
  - Standards on how to implement Portal applications (consistency)
  - Ownership
  - Procedures

**Urgency: to be available for new opportunities: Target 2<sup>nd</sup> Qtr 2008**

***Target for Project approval: May 2008***

***Support / involvement from other associations is required***



Thank you