



Overview of IT systems

Train the trainer on REACH and RIPs
05 – 06 Mar 2008, Cracow, Poland



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IT systems to support REACH for Industry



- IUCLID 5 and REACH-IT WF systems
- ES/CSA/CSR
- Substance inventory Mgt system
- Supply chain communication
- Pre-registration tool
- SIEF Management IT system
- Overview REACH IT systems

RIP 2: IUCLID5 and REACH-IT WF systems (Agency)



IUCLID 5 is:

In Industry:

- The tool for capturing data on chemicals, preparing and submitting dossiers

In the Agency & in the Member States Competent Authorities (MSCA):

- The **central data repository** for all dossiers submitted
- The basis for **dossier compliance** check and **substance evaluation**

Accessed centrally by the Agency & the MSCA personnel

IUCLID 5 is released in June 2007 and can be downloaded from:

http://echa.europa.eu/reach/software/iuclid_en.html

RIP 2: IUCLID5 and REACH-IT WF syst. (Agency)



REACH-IT Workflow system is:

Central IT system of the future European Chemicals Agency
that will support the implementation of the REACH legislation

It includes:

- A **web portal** for submission and consultation of information by industry
- A **workflow system** for full control of all tasks triggered by REACH
- Central database of all information necessary to manage the system (**REACH-IT database**): identification and status of dossiers, decisions, ...
- A **dissemination system** for publishing non-confidential data on the Agency website

RIP 2: IUCLID5 and REACH-IT WF syst. (Agency)



Possibility to do online dossiers in REACH IT

No need for IUCLID 5

Types of online dossiers

- The dossiers that can be created in REACH-IT at EIO:
 - PPORD notifications
 - Inquiry dossiers
- Dossier types to be added after EIO:
 - Substance in Article notifications
 - Classification & Labelling notifications
 - Downstream User notifications
 - Downstream User report (provided this does not include proposal for additional testing on vertebrate animals)
 - Applications for Authorisation

REACH-IT overview – 16 January 2008 *



REACH-IT Workflow system (ECHA):

REACH-IT WF system will be developed in four releases before EIO:

- **Release 0.1** **September 2007**
- **Release 0.2** **End of January 2008**
- **Release 0.2.5** **End of February 2008**
- **Release 0.3** **End of March 2008**

During April and first half of May the final testing and corrections will be executed and by mid May 2008 release 1.0 of REACH-IT will be ready

As a parallel activity, to be ready before EIO, there will be user guides and training material produced and translations of the user interface of the industry related functionality

** - copied from ECHA presentation 19 Dec 2007*

REACH-IT overview - January 2008 *



REACH-IT Workflow system:

All work is now done based on a new revised planning:

- **A focus on key priorities (legal obligations and deadlines)**
- **An extra intermediate release in the end of February 2008 to allow more time for testing**
- **Some functionality is postponed to a date after EIO (e.g. REACH-IT will not provide workflow support for all business presses (SOPs) at EIO)**

ECHA is currently investigating alternative solutions until all workflows can be implemented in REACH-IT

Serious concerns about deadlines, testing by industry,.....
System can only be workable if properly tested with users
Discussion with ECHA initiated

** - copied from ECHA presentation 19 Dec 2007*

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RIP 3.2: IT systems for ES / CSA / CSR (Agency)



ES / CSA / CSR systems include:

IT tools to support the creation of:

- **Exposure scenarios (preliminary / final)**
- **Chemical Safety Assessment, including e.g.**
 - **Estimating modelling**
 - **Risk Characterisation**
- **Chemical Safety Report**

It includes:

- **Capturing data for ES (e.g. Determinants)**
- **Estimating modelling tools for Workers, Consumers, Environment**
- **Standard libraries for e.g. Phrases, RMM ...**
- **Compilation of Chemical Safety Report**
- **Providing Exposure Scenarios to be annexed to SDS (multi-language !!)**

REACH-IT overview – 16 January 2008



ES/CSA/CSR tools (ECHA):

- | | |
|---|-------------------------|
| Analysis phase | - April 2008 |
| Design models / data structure | - April 2008 |
| Aim should be to have working tools in time for the preparation of CSRs, i.e. | - end 2008 / early 2009 |

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REACH-IT Systems Architecture – SIMS (Cefic)



Background: “Scenario work sessions” / Systems Architecture blue print:

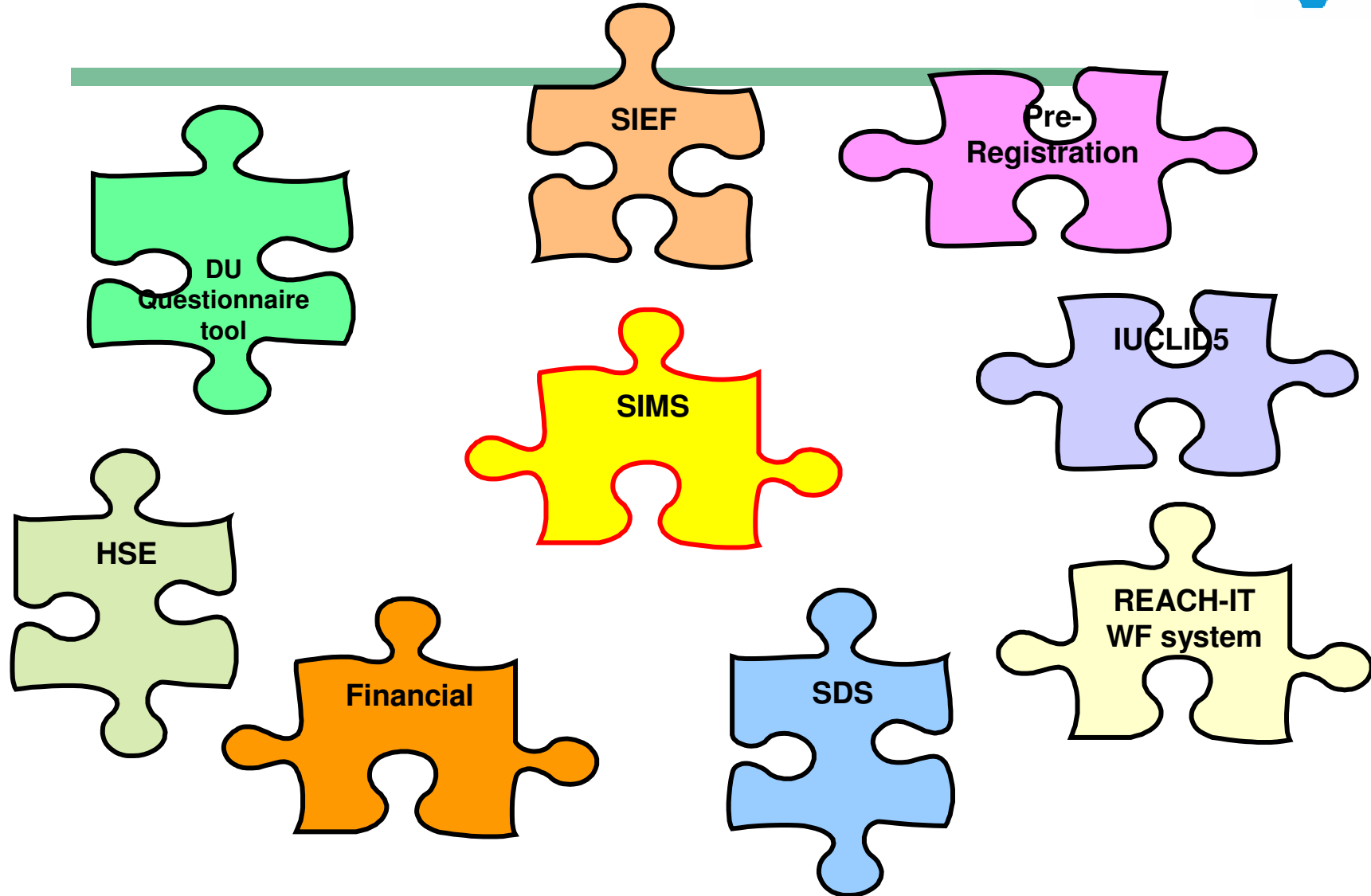
- Gaps identified which are not covered by most systems portfolios:
 - **Substance Life Cycle** (for ALL Substances)
 - **Substance monitoring / tracking** tool for REACH processes
 - Need for **integration**, e.g. Product hierarchy → Substance
 - Supply Chain need to have the whole picture of the production process
 - **Placeholder** for identified data gaps, e.g. Product Type, Substance Type, Substance UUID, REACH status
 - **Source** for submitting data for Pre-Registration
 - Results from SVT
 - Role(s) for a Substance, e.g. DU, M, I

Need for a flexible way to:

- **fit the missing pieces**
- **create an integrated view**

regardless of the ‘existing systems portfolio’  **SIMS**

SIMS - The glue for REACH-related systems



REACH-IT Systems Architecture – SIMS

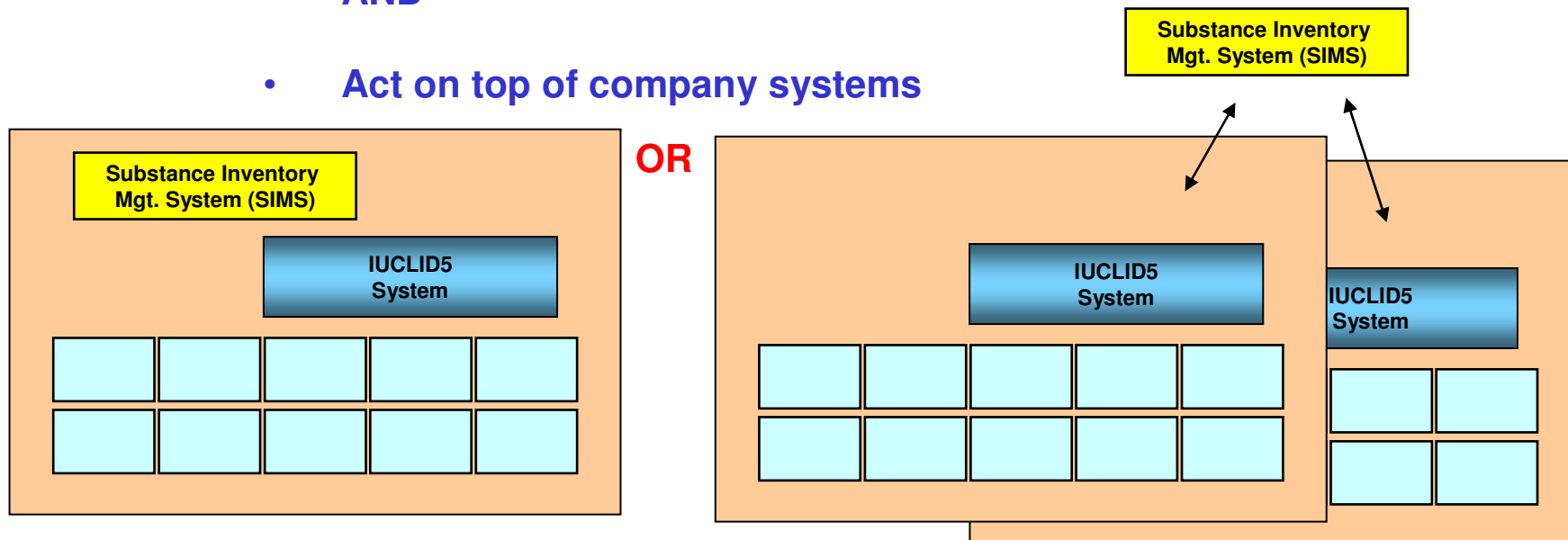


Substance Inventory Management System (SIMS)

- SIMS is needed to be an ‘umbrella’ system / database to:
 - Act as Integrator between several IT systems (ERP, HSE, IUCLID, etc.)
 - Monitor Life cycle of ALL Substances
 - Support REACH processes
 - Reporting tool e.g. for REACH substance tracking

AND

- Act on top of company systems



REACH-IT Systems Architecture – SIMS



However:

No shared project will be launched to develop SIMS as a system or database:

SIMS Target:

- **IT Architecture initiative will deliver a standard data model**
- **Further development of SIMS will be responsibility of companies, IT software providers**

With a standard Data Model, data names, definitions, formats and values will be consistently applied across systems / companies



Data exchange will be straight forward !!

IT systems to support REACH for Industry



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- **Supply chain communication**
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Supply chain communication (Industry)



Communication between actors in supply chain of:

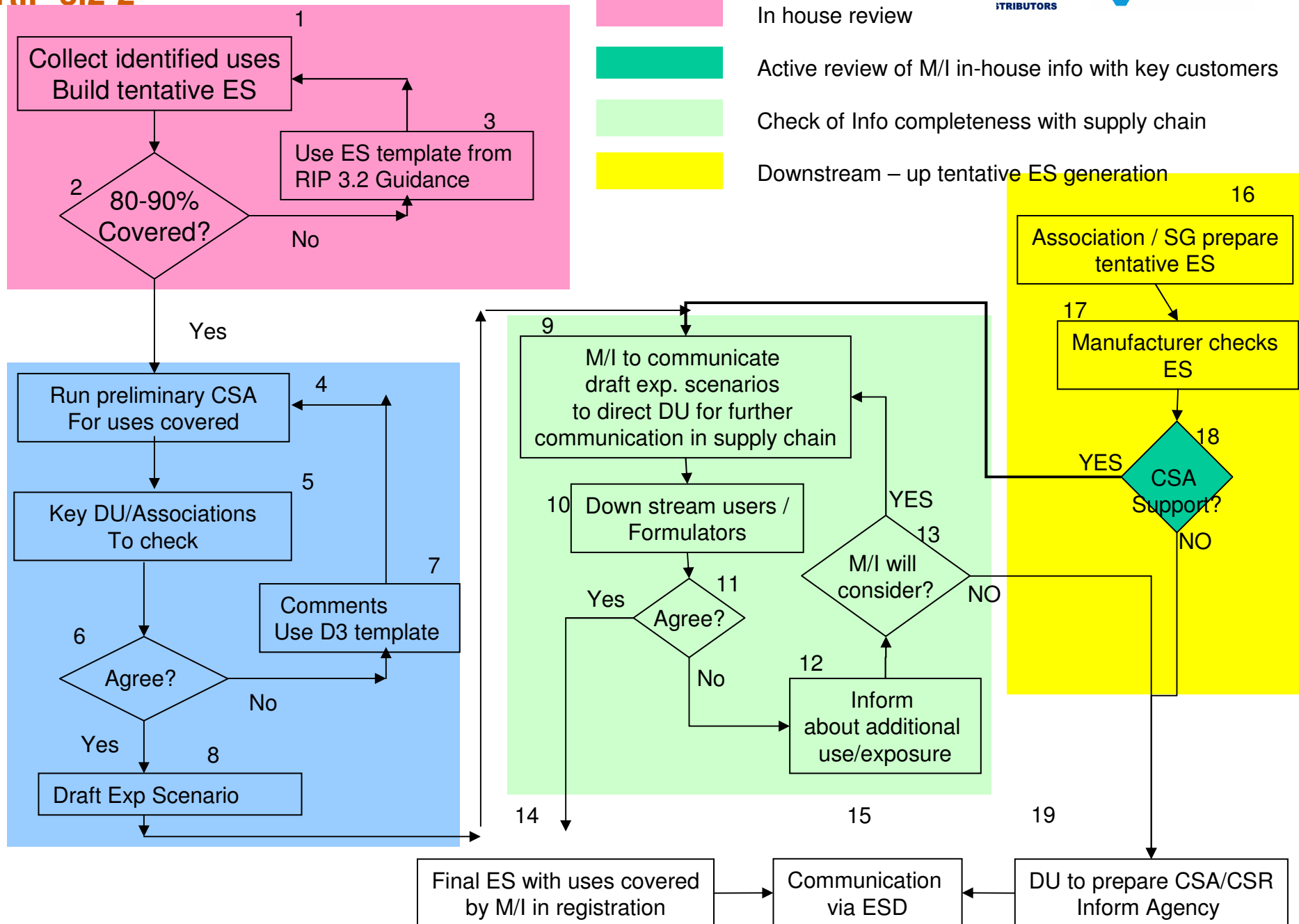
- Use and exposure information
- Exposure scenario's
- Risk management measures

Based on RIP 3.2 guidance

System requirements and questionnaires will be developed.

Available Q2 2008

Workflow Use & Expose Scenario Communication RIP 3.2-2



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RIP 2: IT system for Pre-Registration (Agency)



Pre-Registration system:

IT tool to support the submission of data for Pre-Registration:

- **Data coming from different sources, i.e. IUCLID5, SIMS, other system**
- **Compliant with standard (XML schema) data requirements**

Limited set of data, e.g.:

- **Substance Name**
- **Substance IDs. (EINECS, CAS #)**
- **Company Name / Address / Contact Person**
- **Tonnage band / deadline for registration**
- **3rd Party representative**
- **Substances with similar intrinsic properties**
-

Available: IUCLID 5 Pre-registration XML schemes
In Production: IUCLID 5 Pre-registration Tool (Feb/Mar)

After Pre Registration



Pre SIEF WebPage

- A webpage will be available for viewing successfully pre-registered substances.
- Parties pre-registering same substance are put in touch via the IT system.
- Option to volunteer to be SIEF Formation facilitator.
- Pre-registrants can see contact details of other participants.

- Pre SIEF module testing expected in Apr 2008
- Operational June 2008

IT systems to support REACH for Industry



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SIEF Management IT system

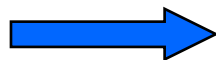
Background:

REACH legislation: Obligation to share animal data and to provide a joint registration

- Pre-registration aims at helping companies to find each other and
- **Substance Information Exchange Fora (SIEFs)** is the mechanism to be used to fulfil these obligations

Commission/Agency obligations:

- Manage Pre-Registration and provide a list of pre-registered substances and contact data
- No involvement in / support to the organisation of SIEFs



Industry to organize SIEF Processing:
(SIEF Formation → Data Sharing → Joint Submission)

SIEF is a new and untested concept requiring new types of co-operation and we risk chaos without **consistent Processes and Tools**

SIEF – Potential impact for industry



Without any (technical) facilitation:

- SIEF partners to find out how to interact / collaborate
- Inconsistent / fragmented processes and procedures
- Variety of IT tools on the market, to be used across companies
- Security handled for each system → low quality / trust
(30.000 SIEFs – Avg. 5 members → 150.000 SIEF users)

How to address:

- Develop a common SIEF IT platform
- Broad industry support required
- Single platform will save time / money
- Integrated security

However: Other SIEF IT systems may / will exist



SIEF Mgt. IT system - Proposal

Cefic and National Federations have started company ReachLink to develop industry wide SIEF IT system:

- Collaboration tools (e.g. chat box, discussion forum)
- SIEF Formation, Data Exchange, prepare Joint Submission
- Secured access to information
- Low license cost (no barrier for SMEs)

Operate and maintain IT platform:

- Contracted with IBM

Timing:

- Operational by 1 June 2008 !!

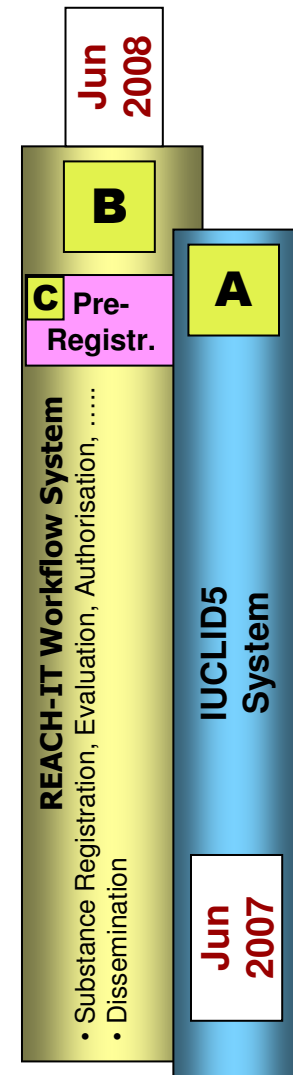
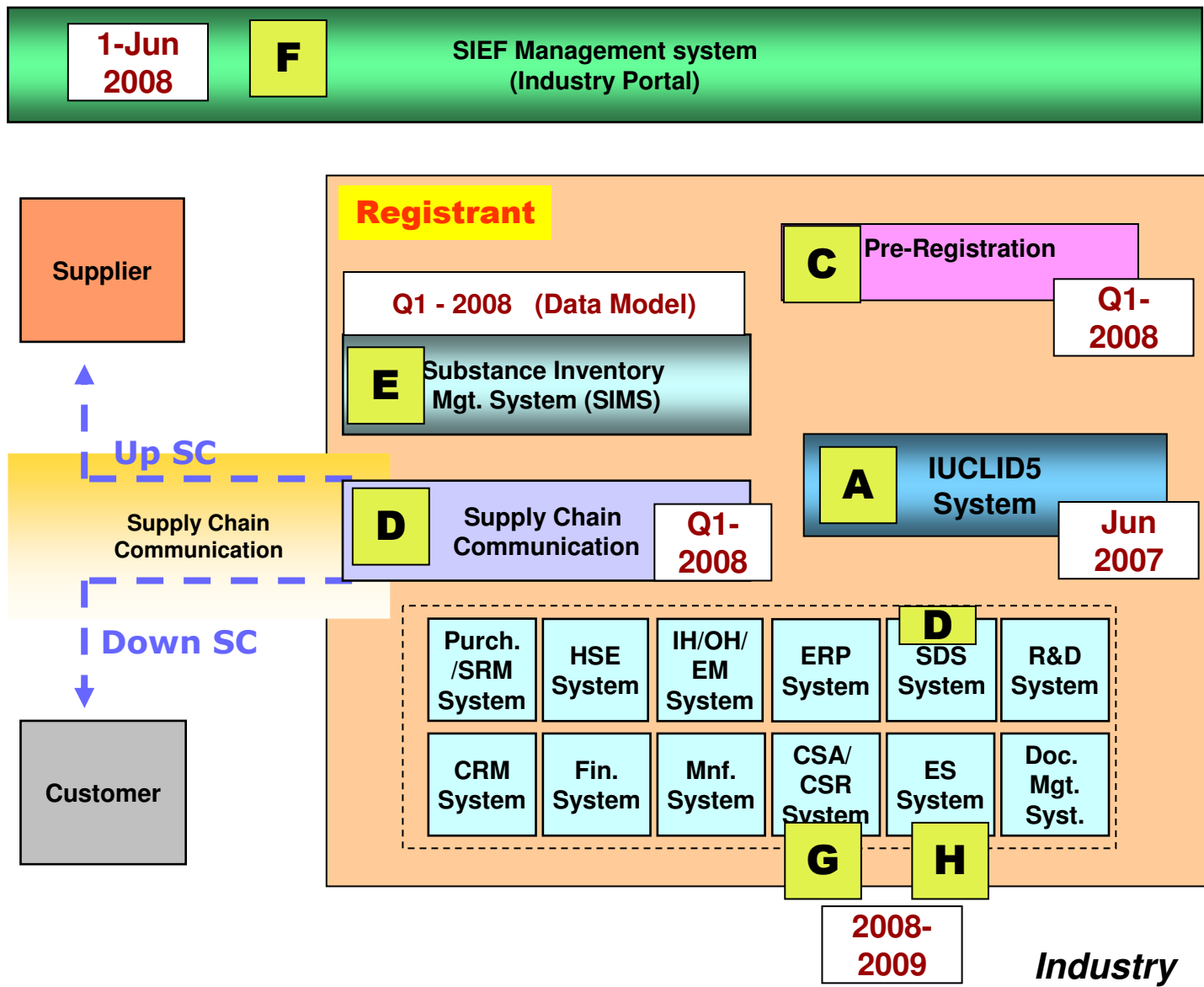
Note: Industry Portal design will enable future additional functionality (e.g. for Supply Chain communication data)

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Thank you