

How does industry prepare for pre-registration

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REACH Workshop- Final countdown to pre-registration
and registration of chemicals

Monday 14 April 2008, Brussels - Belgium



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Outline

- What has industry done to prepare for pre-registration and registration – an example
 - Inventory
 - Substance identity
 - IUCLID 5 downloads
 - SIEF planning
 - Communication in the supply chain
- What have industry associations done to inform companies, in particular SMEs, about pre-registration?



Product Compositional Data

EINECS, ELINCS

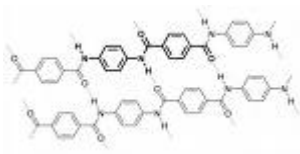
Polymer, NLP

REACH deals with substances

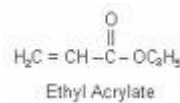
- Tens of thousands of substances

Industry works primarily with products

- Millions of products
- Use of products in products
- Product safety driven



Kevlar



REACH requires the development of approaches to deal with substances in products

- Substance inventories

Understand your organisational structure

REACH deals with Legal Entities

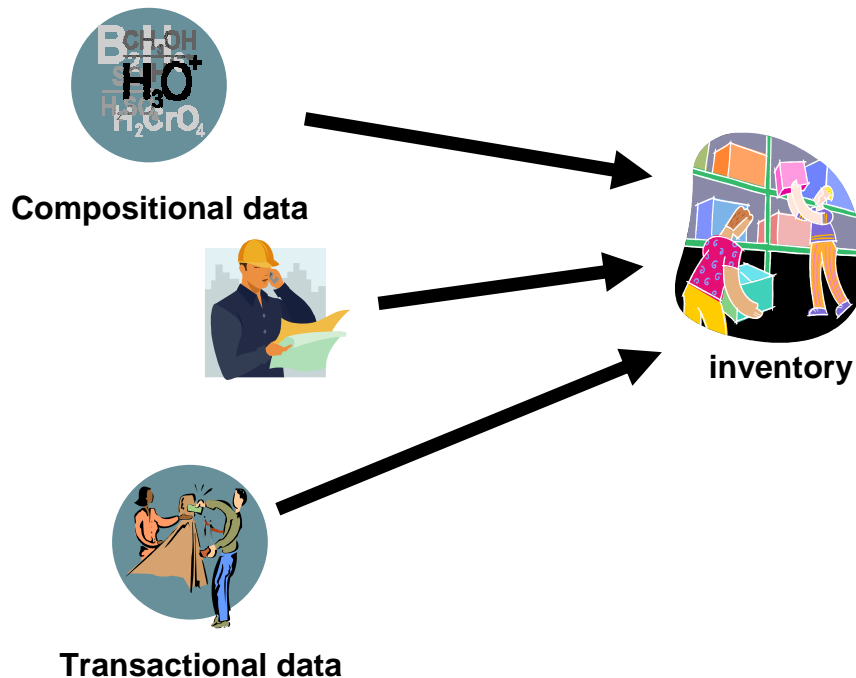
- Country specific boundaries

Industry often works with business units

- No geographical boundaries - across Europe
- Within one country a Business Unit can own multiple Legal Entities
- Multiple Business Units can work within one Legal Entity

Develop your substance inventory

- A “real-time” or “as-is” reflection of substances one is dealing with
- More than one purpose:
 - Starting point for pre-registration
 - Starting point for classification and labelling inventory
 - Support Operations
 - etc.

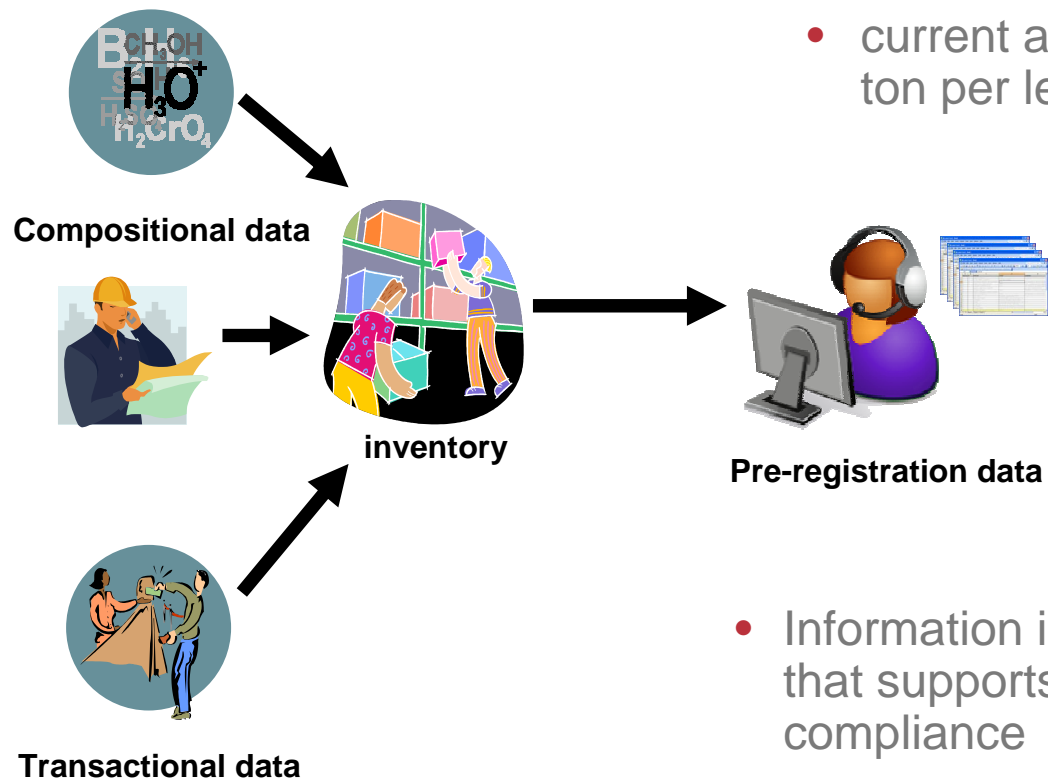


- Create and maintain lists of substances that are:
 - Imported into the EU
 - Manufactured in the EU
 - Used as a Downstream User in the EU
 - **no volume cut-off**

Inventory system should include Legal Entity & Substance Volume Tracking

Build your pre-registration list

- Extract from the inventory a list of substances that have to be pre-registered:
 - import into EU
 - manufacture in the EU
 - current and expected annual tonnage above 1 ton per legal entity



- Information is a starting point to set up a system that supports pre-registration for REACH compliance

Populate internal pre-registration database

The following fields could be filled-out:

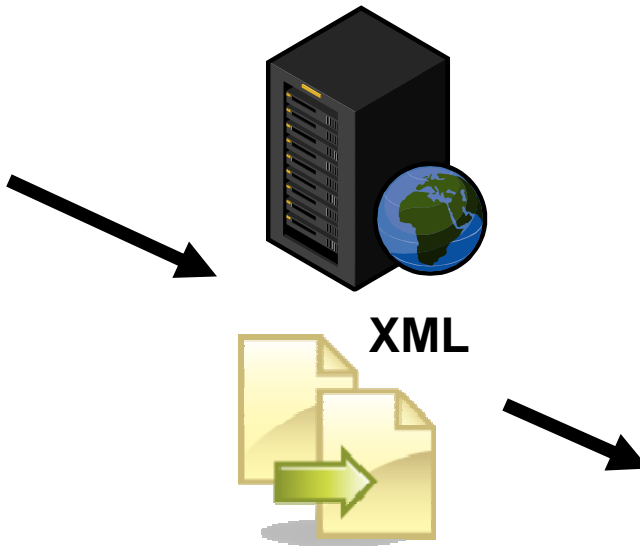
- IUPAC name of the substance
- CAS number of the substance
- EINECS number of the substance
- The tonnage band and the envisaged deadline
- Redefinition of a substance
 - in relationship to CAS or EINECS entries
- The legal entity information
 - Footnote – Substance read-across is an approach to fill information gaps. The information gap filling strategy is preferably decided upon within the SIEF

General Information			Substance Information							Corporate Inveture
Preformal SBU (Name)	Business Entity	Contribution to pre-registr (Y/N)	Substance name	Volume (kg)	IUPAC name	Re-Defined Substance (Y/N)	EC number	CAS number	Shared substance (Y/N)	
1	2	3	4	5	6	7	8	9	10	11

Submit pre-registration information to Helsinki

General Information			Substance Information						Corporate mentions	
Platform SBU (name)	Business Entity (code)	Contribution to pre-register (Y/N)	Substance name	Volume Entry (DT)	Volume ALPAC (name)	Relevant Substance (Y/N)	EC number	CAS number	Shared substance (Y/N)	CC
1	2	3	4	5	6	7	8	9	10	11

Internal database



ECHA



As of 1 June 2008

Plan for pre-registrant activities

Pre-registration

- CAS or EINECS-identifier
- Access to Legal Entity contact information

'Information exchange' on:

- Chemical identity
- Volume of production (tonnage band)
- Hazard information?
- Uses (in registration consortia)?
- Exposure data (in registration consortia)?

Potential risk of:

- Infringements of anti-competition law
- Loss of Intellectual Property and CBI (Confidential Business Information)



Prepare for Substance ID

- First step following pre-registration
- Objective: agree on sameness of substance
- Pre-registration list
 - CAS or EINECS-identifier
- Guidance on substance ID (RIP3.10)
 - Well-defined substances
 - Mono-constituent substances
 - Multi-constituent substances
 - Substances with Unknown or Variable composition, Complex reaction products or Biological materials (= UVCBs)

RECHA

Guidance for identification and naming of substances under REACH



June 2007

Guidance for the Implementation of REACH



Prepare for data sharing

Data sharing

- One of the first steps following the birth of the SIEF
- Legal requirement to inform other pre-registrants in the SIEF of available data

What?

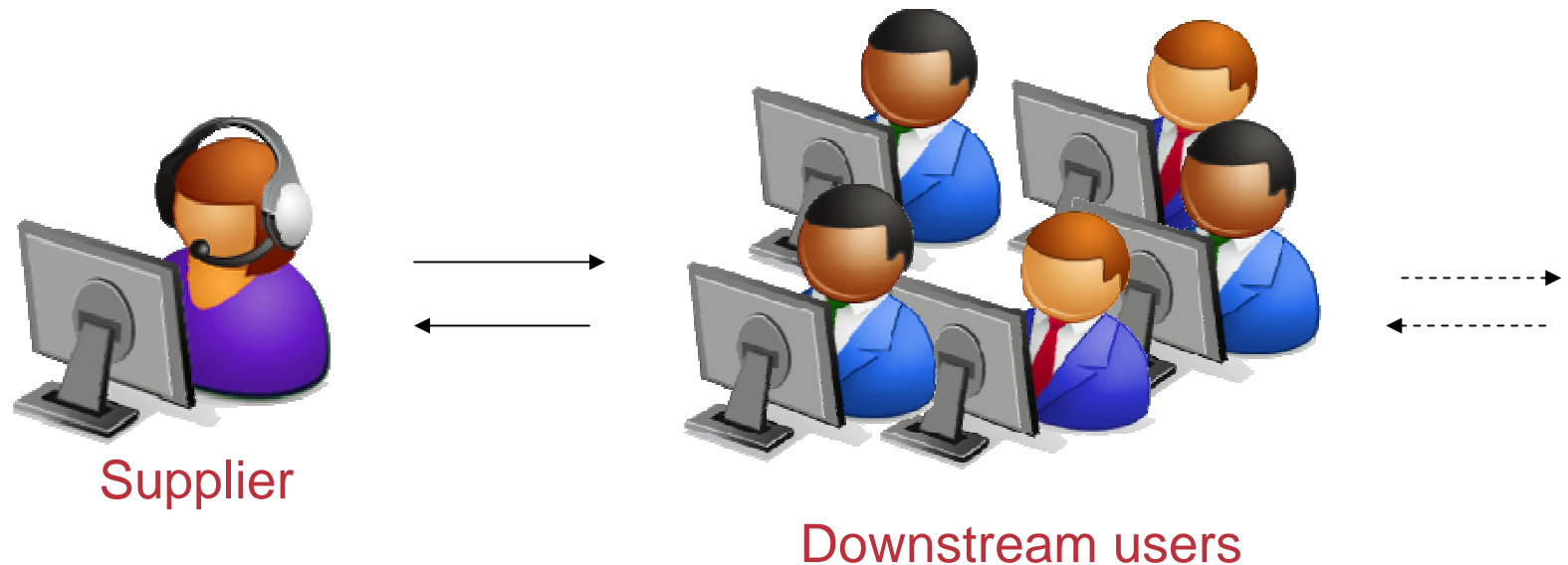
- Identify information one owns (or may have access to)
- Collect test reports
- Prepare (robust) study summaries in IUCLID 5
- Assess quality of the information
- For Klimisch 1 and 2 studies: determine costs

Prepare for registration – IUCLID 5

- Create internal IT-architecture
- Download IUCLID 5
- Build capacity and capability with business, technical and regulatory personnel
- Develop substance identification
- Gather information on manufacture and use
- Create (robust) study summaries of own hazard data
- Store relevant information



Communicate with your supply chain



- Pre-registration is necessary to be able to continue business
 - No data, no market
 - Avoid “Panic pre-registration”
 - Late pre-registration

Make use of industry awareness actions

- Information bulletins
- Newsletters
- Fact sheets
- Interpretations
- Guidance/guidelines
- Workshops
- Seminars
- Trainings
-



ACEA
EUROPEAN AUTOMOBILE MANUFACTURERS' ASSOCIATION



Association Internationale de la Savonnerie, de la Détérgence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products



Be Aware of REACH!

- Inventory of substances
- Pre-register manufactured or imported substances
- REACH-IT tool from ECHA
 - release ASAP, together with guidance
 - companies need time to experience and train
 - proof of pre-registration -> pre-registration number
- No need for 'panic pre-registration' by multiple players in the same supply chain
 - consider late pre-registration possibility
- Prepare for SIEF discussions and information exchange



Ferocactus wislizeni

Beyond being a regulatory compliance issue, REACH is a business issue



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