

# **The Practicalities of REACH Business Planning to Registration**

U.S. Commercial Services Webinar

**EU REACH – WHAT YOU SHOULD BE DOING NOW**

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# Overview

- Introduction
- Understanding the implications before you start
- Potential costs
- Your legal entity in Europe
- The Only Representative, what, who and why
- Finding the data and you need - co-registrants and SIEFs
- Preparing and submitting your dossier
- Post registration



# Introduction



- Who we are
  - Brussels based Consultancy
  - Many years of chemical and oil industry experience
    - Toxicology, Regulatory, IT and Technical Managerial roles in major multinationals
  - Strong Technical, IT and project management teams
  - Strategic alliances to cover any scale of project

Toxicology and  
Environmental  
Services

Training Services

Product Steward  
Services

Managed  
Services

Consortia  
Management  
Services

# Understanding the implications before you start

- The Regulatory Context - “No data – No Market”
  - Registration Evaluation Authorisation\* and Restriction of Chemicals
    - (EC) No 1907/2006
  - All substances manufactured within or imported into European Economic Area at more than 1 tonne per annum to be registered at European Chemicals Agency (ECHA)
  - Replaces 40 pre-existing European Directives on
    - Chemical Risk Assessment
    - Supply Chain Communication
      - E.g. provision of Safety Data Sheets to customers



\*For the most hazardous substances

# Understanding the implications

- Practical
  - Registration types
  - Exemptions
  - Deadlines based upon tonnage
  - Requirement to work with coproduces / importers
  - Uses must be registered for business continuance
  - Covers both intrinsic hazard and risk
  - Electronic data entry and Registration process
  - Registration Fees
- 28,000 pages of text, guidance
- Regular updating of guidance, systems and interpretation
  - Registrant to keep submissions updated – hazard and use
- Complex, Resource intensive, Ongoing
- Costs 30€ – >500k€ - per substance
- Impacts ~ 30,000 chemical substances >1tpa

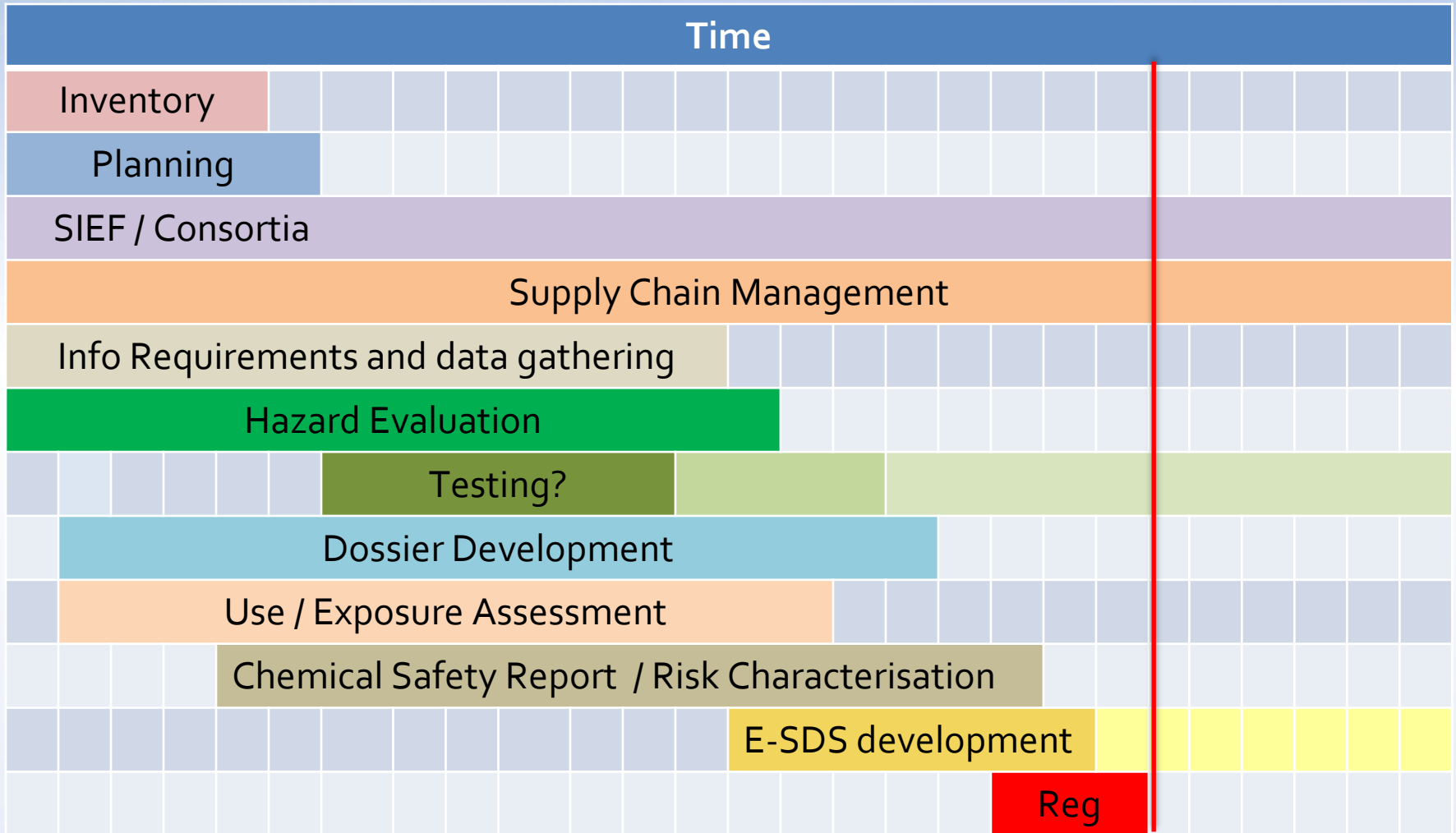


# Some common jargon

- Substance Information Exchange Forum (SIEF)
  - Grouping of potential registrants of the same substance - for data sharing
- Consortium
  - Grouping of potential registrants of same / similar substances - for developing the dossiers within a contractual framework
- Registration dossier
  - The information that is submitted to ECHA
- Information Requirement
  - The proscribed intrinsic properties (Phys chem , Env, Tox endpoints) detailed in the REACH annexes - tonnage dependant
- Iuclid
  - Software required to collate and submit data
- Robust Study Summary
  - The format in which the intrinsic properties data need to be written
- Chemicals Safety Assessment
  - Assessment of intrinsic properties and Classification and Labelling
- Exposure Scenario
  - Description of the conditions of controlled use of a substance with Risk Management measures (RMM)
- Chemical Safety Report
  - CSA + risk assessment / Exposure scenarios



# Indicative practical planning steps



# Understanding the Implications Lessons from 2010 Registrations

- Don't underestimate workloads and complexity
- Organize early
  - Phase 2 - Less than 2 years remaining to develop:
    - Business case and budgets
    - Science case
    - The Registration dossier!
  - Who will do what?
    - Partners and co-registrants?
    - Consultants/contractors
- Consider the Business aspects
  - Registration is your licence to operate
    - No data, no market
  - Costs of REACH are highly variable
    - Consider ROI



# Understanding the implications

## Costs

### Factors that Affected Costs



Data available

Few data

Data in public domain

Proprietary data

Co-registrants

Single registrants

Agreements in place

Lengthy contract discussions

Early planning

Last minute rush

Not Classified as hazardous

Classified as hazardous

Uses / site limited

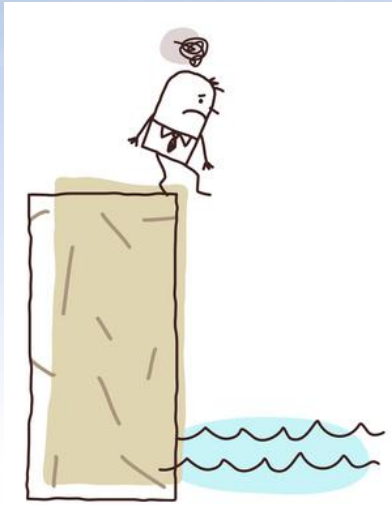
Many uses

Agreed science positions /  
classification

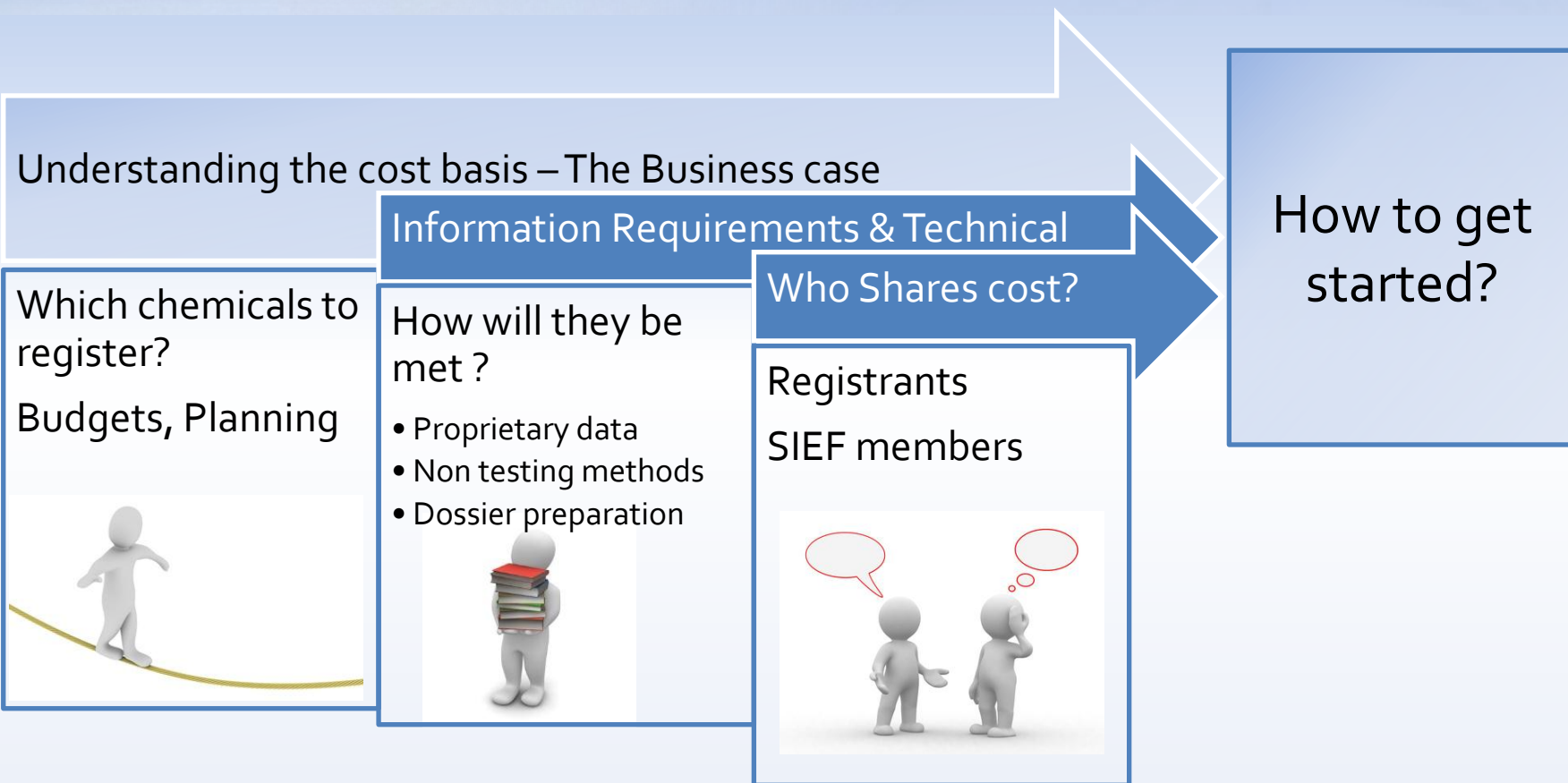
Disagreement / debate



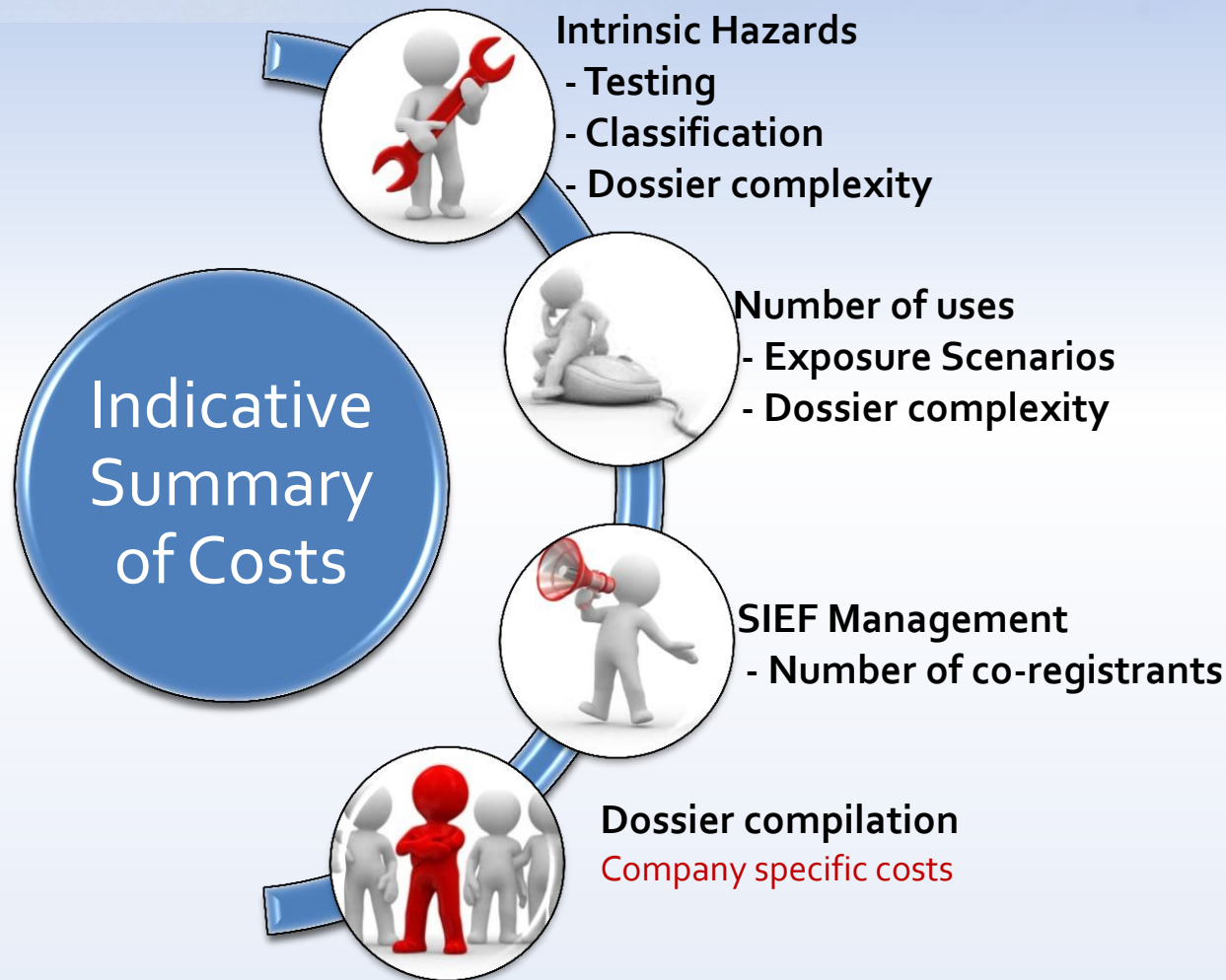
# Building the business case



# Preparing for 2013 and 2018 Registrations



# Determining Costs



e.g.  
REACH  
Cat Tool  
PC / ICFI

# Your legal entity in Europe

- EU regulation can only apply to a EU legal entity
- Responsibility for REACH
  - with EU Manufacturer or Importer
- Non-EU companies
  - Not able to register directly
  - Needs appoint a single representative in Europe
    - The Only Representative – “OR”
- OR can be an EU affiliate /subsidiary of the supplier.
- OR takes on duties of a Manufacturer / Importer
  - Compliance
  - Hazard Communication
  - The supplier need not share confidential information with an importer

# Your legal entity in Europe

EU regulation can only apply to a EU legal entity

Legal Responsibility for REACH

- with EU Manufacturer or Importer

Consequently - Non-EU companies

- Not able to register directly
- Need to have a single representative in Europe

**The Only Representative – “OR”**

- Legal construct under REACH
- Can be an EU affiliate /subsidiary of the supplier or appointed 3<sup>rd</sup> Party.

**Takes on duties of a Manufacturer / Importer**

- Compliance
- Hazard Communication
- The supplier need not share confidential information with an importer

# Only Representatives - what the text says

## REACH Article 8 - Only representative of a non-Community manufacturer



### Article 1

#### Ability to appoint

*A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.*



### Article 2

#### Duty to comply and keep records

*The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.*



### Article 3

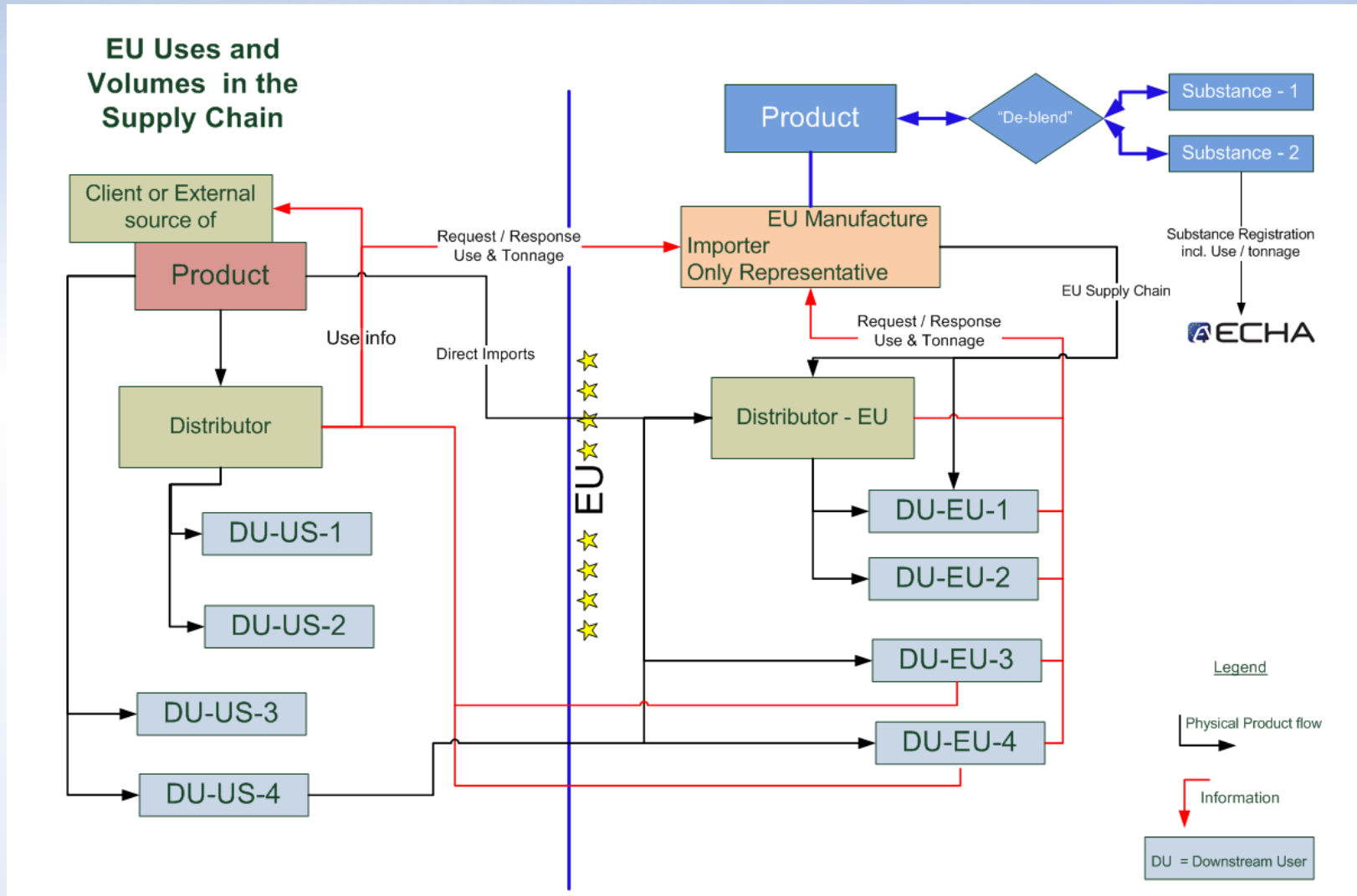
#### Inform other Importers of your substances

*If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.*

# Only Representatives - Complications

- REACH Art. 8 implies a simple supply chain: supplier - importer – end user.
- End users may purchase from many suppliers; importers may source from more than one supplier; the supplier may be an export company buying from various sources before shipping to Europe

# ORs and complexity of the supply chain



# Work done by an OR

- Make the registration to ECHA and pay the fees
- Responsibilities that may be done by OR
  - Role within SIEFs - agree
    - Hazard Assessment
    - Information requirement and cost sharing data
      - testing strategies if required
  - Work with importers and other Downstream users (DUs)
    - Collect uses of DUs ....
    - Monitor supply patterns
      - (volumes of import by each importer,
  - Chemical Safety Report
  - SDSs to be consistent with Registration details
  - Ensure Risk Management Measures are being communicated

# Finding an OR

- Dependant upon level of service required
  - Not all have all the technical / skills
  - Mailbox to active participant in EU
  - Range from independents, Legal firms to large CROs
- Some heavily advertised...
- Need to consider
  - Level of understanding – technical / legal
  - If they understand your business
  - Will be around in future years
  - Level of service required
  - Current and future costs
  - Confidentiality

# Finding the data and you need

## Co-registrants and SIEFs

- REACH requires one registration
  - Lead company submits all the intrinsic hazard data
  - Co-registrants submit on their own data in
    - Substance Identification
- ECHA – REACH IT
  - Provides mechanism to find other interested in the same substance
- Requires someone to take the initiative...

# Lead Registrant and co registrant dossiers



1. Substance ID,  
Composition, analytical

2. Classification and Labelling

3. Manufacture, use, exposure

13 – CSR Part A + specific aspects



Every Registrant  
Company data

2. Classification and Labelling

4. Phys chem properties

5. Environmental fate

6. Ecotox

7. Guidance on safe use

:

13. Assessment reports

CSR Part B



Lead Company  
submits

Co-registrants refer

SUBJECT TO INTERESTS OF  
SIEF MEMBERS (intermediate vs.  
substance) AND DATA RIGHTS

Common elements of the  
extended Safety Data Sheet  
- Exposure Scenarios

Every Registrant  
SDS or communication

# Preparing and submitting your dossier



- A multi stage process
  - Driven by business requirement, legal text and guidance
  - Requires a detailed technical plan
  - Needs to be integrated with potential co-registrants / SIEF members
  - Needs to be owned

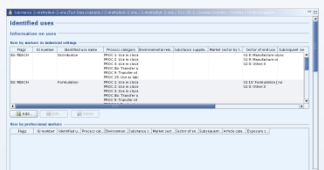
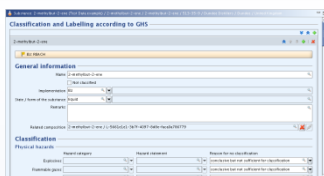
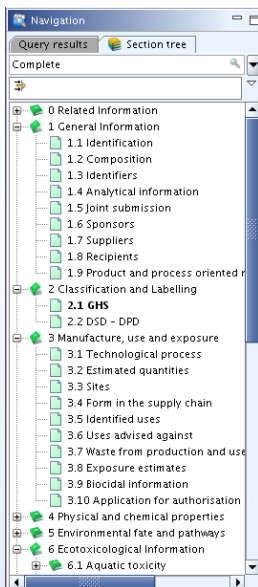
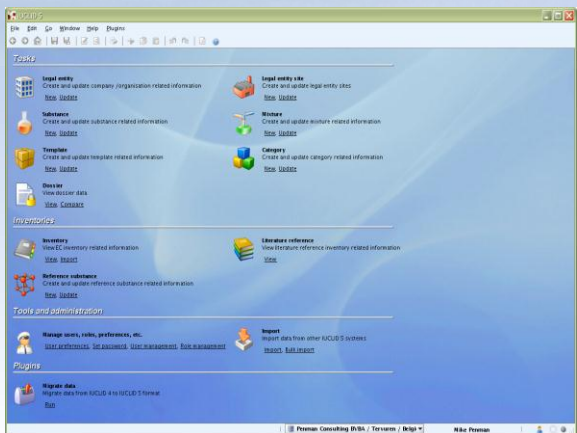
	Ⓜ	Name	Du
1		⊕ General Technical Activities	51.
12		⊖ Substance / Category Specific planning	12
13		⊕ Gather Information	45.
21		⊖ Initial Data Review, Gap analysis and Test Plans	10
22		⊕ Review information - fit for purpose? - Klimish scores - record in common IUCLID	
26		⊕ Apply Annex XI / read across / waivers for gaps where viable	1
32		⊕ Develop testing proposals if needed	
44		⊕ Confirm viability of Categories	8.0
47		⊖ Prepare IUCLID5 datasets for substances / Categories	2
48		⊕ Robust summary preparation and inputting (4 or 6-8 weeks)	2
55		Build / populate categories (in parallel with data entry)	
56		⊕ Prepare Endpoint study Summaries and conclusion on - CLP, DNELS, PNEC, PBT	
69		⊕ Review Conclusions on Data summaries and associated conclusions - PNECs, DNELS	2
75		⊖ Exposure and use	
76		⊕ Colate uses for substance(s)	
80	⚠	⊕ Run Exposure models - Tier 1	
88		⊕ Perform Risk Characterisation	
91		⊕ Prepare final CSR	63.9
97		⊕ Indicative SDS Production	10
103		⊕ Membership / TC review of dossier, CSR and SDS	
106		⊕ Finalisation and sign off	
115		⊕ Dissemination process	





## Required for data entry and submission

- Submission of all registration information to REACH IT
  - Legal entity
  - Substance ID + analytical
  - Uses
  - RSS of intrinsic hazards
  - Testing proposals
  - Safe Handling and use
- Upgrades released regularly
  - Latest version needed for submission and updated submissions
- Intention to integrate further with exposure and risk assessment tools Q1 2012?



# Post registration

## Demonstrating and Keeping in Compliance

- Enforcement is high on EU political agenda
  - EU forum on the enforcement activities
  - Downstream users demanding demonstration of compliance from registrants to ensure their own business continues
- Ongoing compliance needs proactive approach
  - In manufacturing operations
  - Up and down the supply chain
  - Changing volumes / Uses
  - Intrinsic properties
  - Changing legal ownership
  - Changing uses and new assessments
- Audits will require demonstration of policies and procedures to steward both products and processes



# The steps towards REACH registration



- Thank you for your attention
- Questions?
- Further information?

# More information and Contacting us

- [www.penmanconsulting.com](http://www.penmanconsulting.com)
- [Info@penmanconsulting.com](mailto:Info@penmanconsulting.com)

The screenshot shows the Penman Consulting website homepage. At the top, there is a navigation bar with 'HOME' on the left and 'Font resize: A A A' on the right. Below this is a blue banner with the Penman Consulting logo on the left and the text 'Expertise - Stewardship - Compliance' on the right. The main content area is divided into several sections. On the left, there is a 'Site Menu' with links for 'Penman Consulting', 'Who We Are', 'Services', 'Partners', and 'Contact Us'. Below the menu is a 'Login' section with fields for 'Username' and 'Password', a 'Remember Me' checkbox, and a 'Log in' button. There are also links for 'Forgot your password?', 'Forgot your username?', 'No account yet?', and 'Create an account'. The main content area features a large banner with the text 'More Than 500 Registrations' and an image of paint cans. Below this, there are two columns of text. The left column is titled 'H4R Consortium' and contains the text 'Click here for information about the H4R Consortium, managed by Penman Consulting.' The right column is titled 'Webinar Announcement' and contains the text 'REACH – Developing the Business Case for Registration REACH experts from Penman Consulting and our partner ICF International will show how costs can be forecast using our novel tools and experience from putting together literally hundreds of dossiers resulting in successful registrations...'. Below these columns is a section titled 'Penman Consulting' with a paragraph of text and a list of links: 'LOA REACH Consortium (Lower Olefins and Aromatics)' and 'HOPA REACH Consortium (Higher Olefins and Poly Alpha Olefins)'. This is followed by another paragraph and a section titled 'How We Can Help You' with a paragraph and a list of bullet points: 'We can tailor-make your REACH, GHS and other regulatory solutions.', 'Call on our regulatory advice, product stewardship expertise, detailed planning and action-management.', 'You can use I.T tools to respond to regulatory developments; we give advice and practical help with design, implementation and integration.', and 'We develop strategies to collect toxicological and environmental data for use in risk assessment, to ask and answer questions on chemical safety.' Below this is a link 'Find out more About Penman Consulting.' At the bottom of the page, there is a dark blue footer with four sections: 'NEWEST ITEMS' with a link '> Welcome', 'MOST READ' with a link '> Welcome', 'THIS IS MODULE 8' with the text 'This is one of the lower module slots. Our custom content or specialist', and 'SEARCH THIS SITE' with a search input field and a 'search...' button.