

---

# REACH: It's not too late to get it right

## Help based on real experience



**U.S. Toll-free:** +1-800-504-8071  
**Belgium Toll-free:** 080039119  
**U.K. Toll-free:** 08004960579

**Participant code:** 9343891

**Phone lines will open at 9:55 a.m. EDT**

**Mike Penman**  
**Lucas Bergkamp**  
**Baxter Jones**

**Penman Consulting, Brussels**  
**Hunton & Williams, Brussels**  
**ICF International, Washington, D.C.**

22 July 2009

**ICF**  
INTERNATIONAL®

HUNTON &  
WILLIAMS

**Penman**  
Consulting BVBA

# Ground Rules and Procedures

---

- **Phone lines will be muted.**
- **Submit questions using the question box at the top of your screen.**
- **<F5> to expand slides to full screen. <esc> to restore**
- **The webinar will be recorded and archived for later viewing**

# Today's Presenters

---



## Featured Speakers

**Mike Penman**, Founder, Penman Consulting

**Baxter Jones**, Senior Vice President, ICF International

**Professor Lucas Bergkamp**, Partner, Hunton & Williams

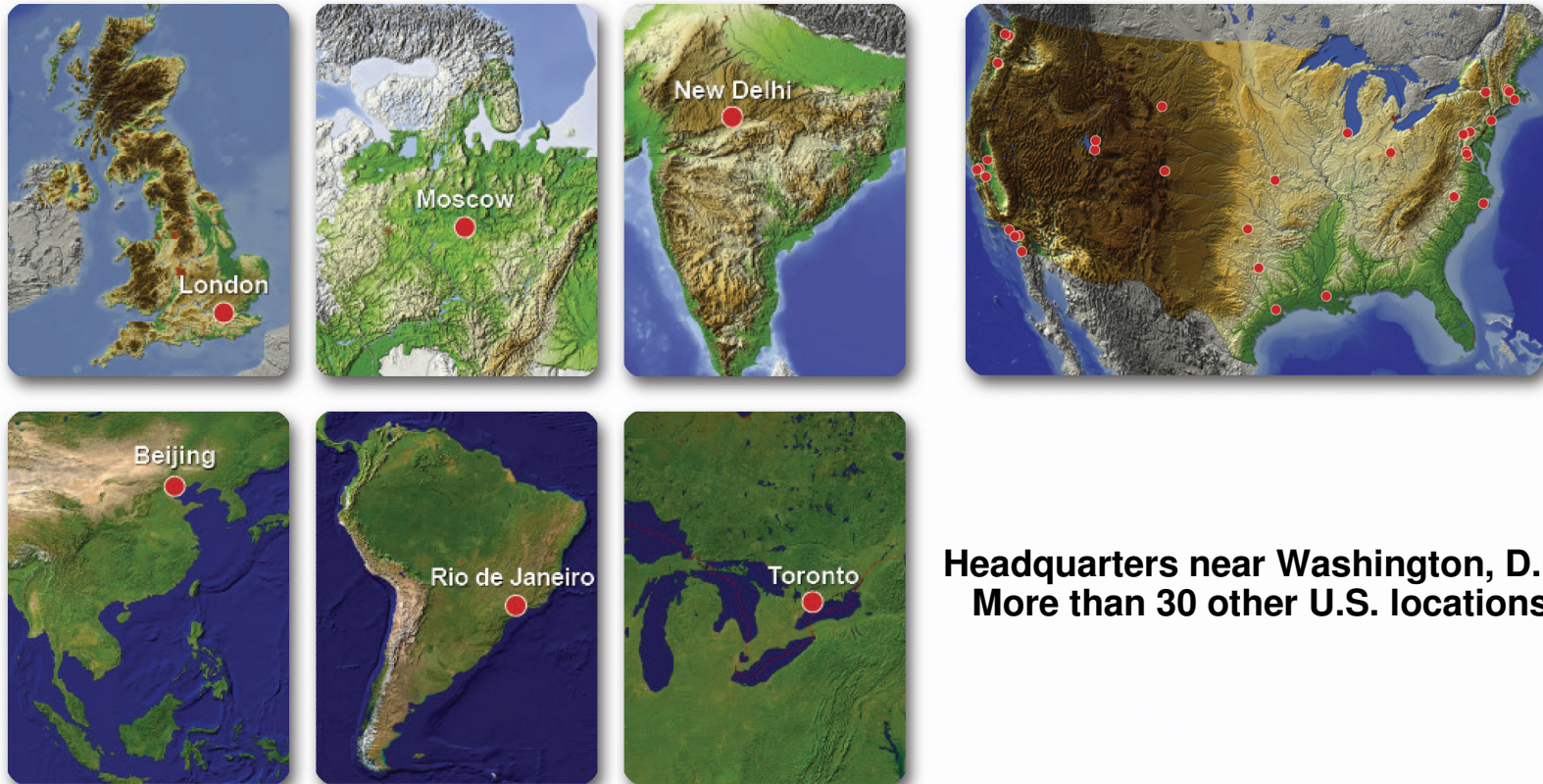
## Moderator

**Jay Hadley**, Vice President, ICF International



# ICF International Overview

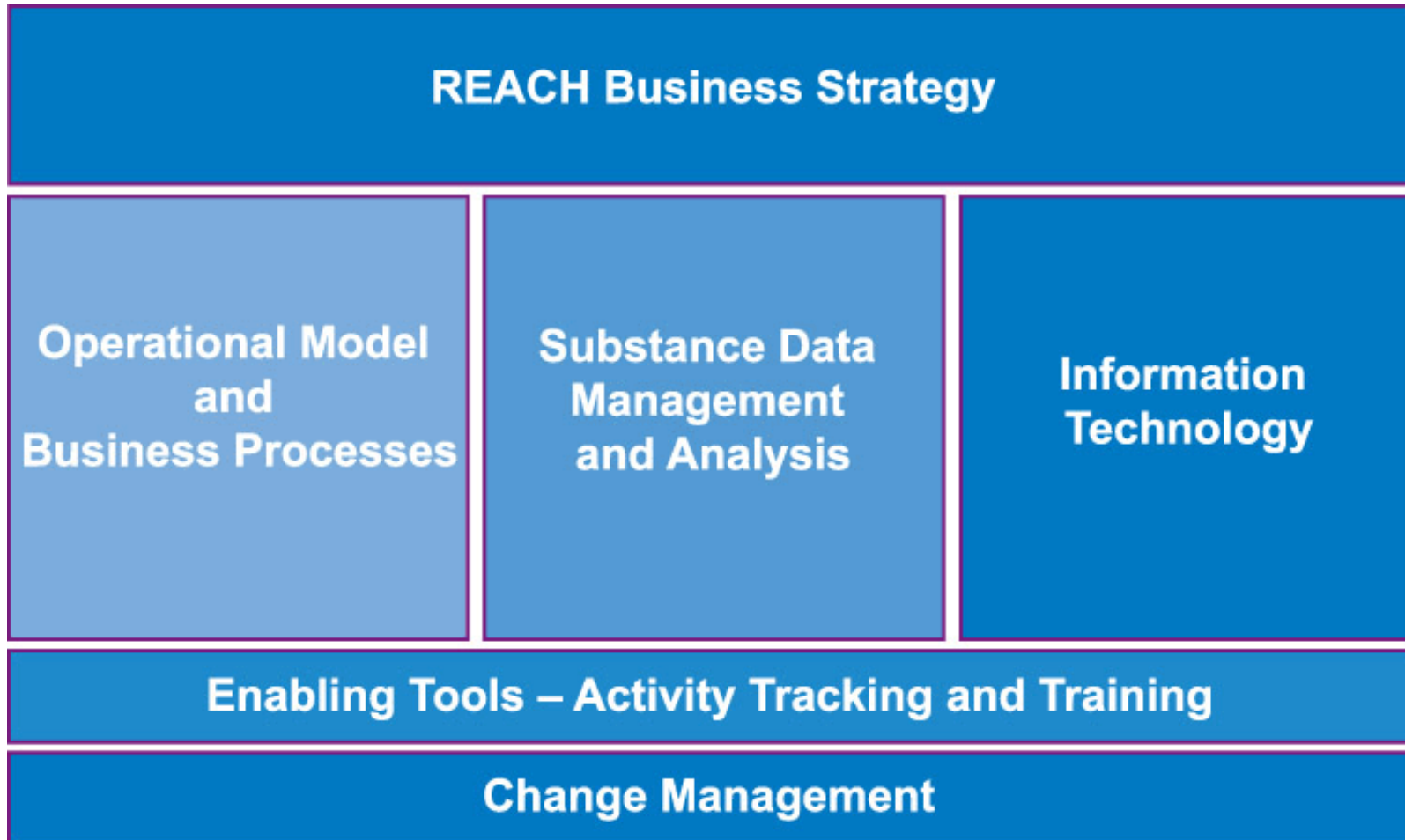
---



**Beijing • Brussels • London • Moscow • New Delhi • Rio de Janeiro • Toronto**

# Integrated Approach to REACH

---



# Introduction – Penman Consulting

---

- **Penman Consulting**

- **Finding and linking with other skilled resources to manage complex scientific and regulatory projects**
  - **Large REACH Consortia under management - over 200 substances**
    - **Project management, legal, financial, technical aspects**
  - **Range of industries**
- **Mike Penman - over 30 years global experience**
  - **Toxicology / Industry regulatory background**
  - **Chemical and oil industries**
  - **Chair industry groups - Technical task forces**
  - **Development of enabling tools**

REACHsuite 

# Why We are Here - Overview

---

- **REACH: Current State**
  - Timelines and requirements for REACH registration
  - What has to be done
- **Your Critical Chemistry at Risk?**
  - Are all of your substances on track?
  - Characteristics and strategy
- **REACH Challenges**
  - Technical and Scientific
  - Resource Constraints
  - Legal
- **Solutions**
  - Organisational
  - Strategies and Tools
- **Conclusions**

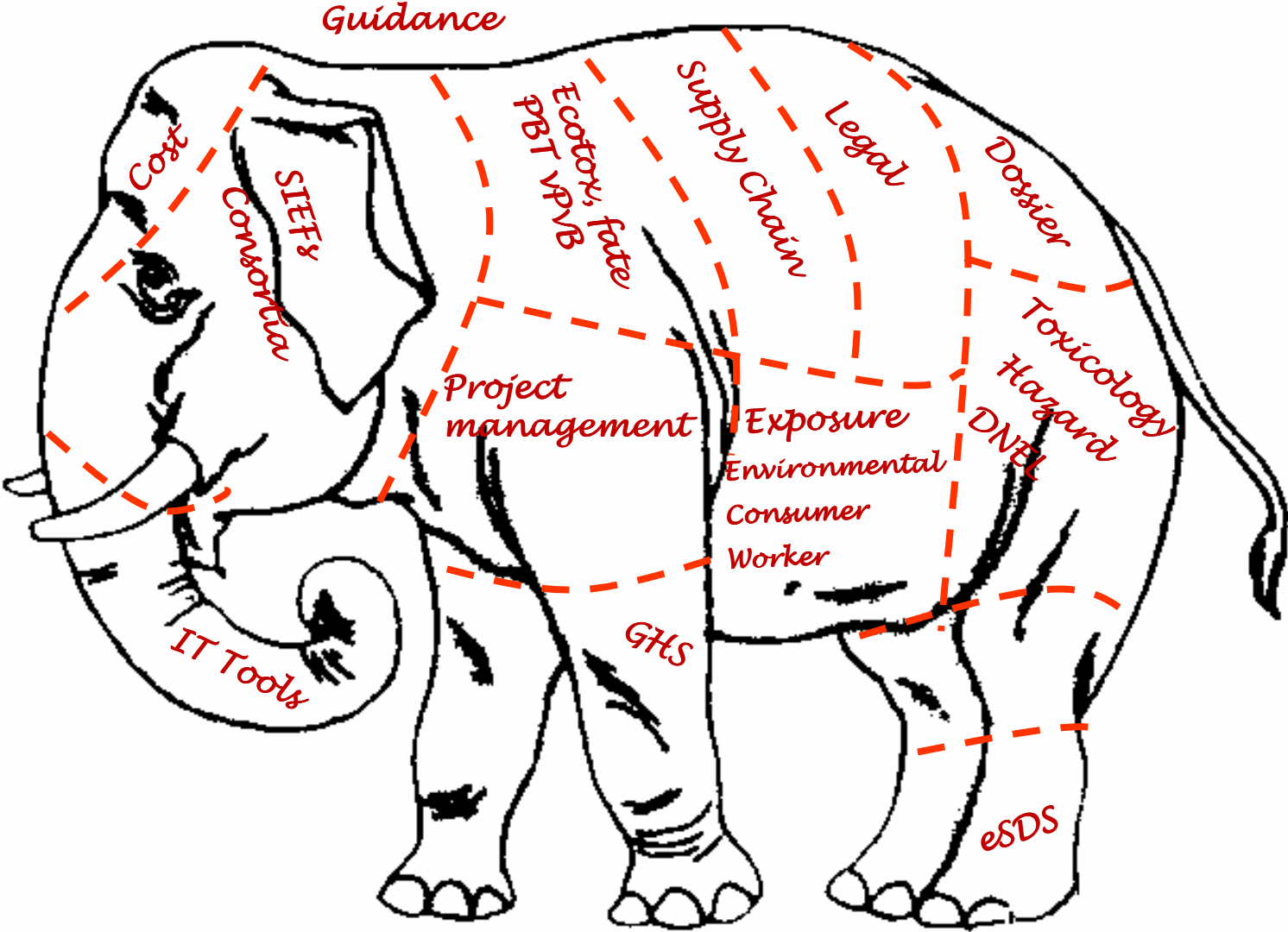
# Where To Start?

---

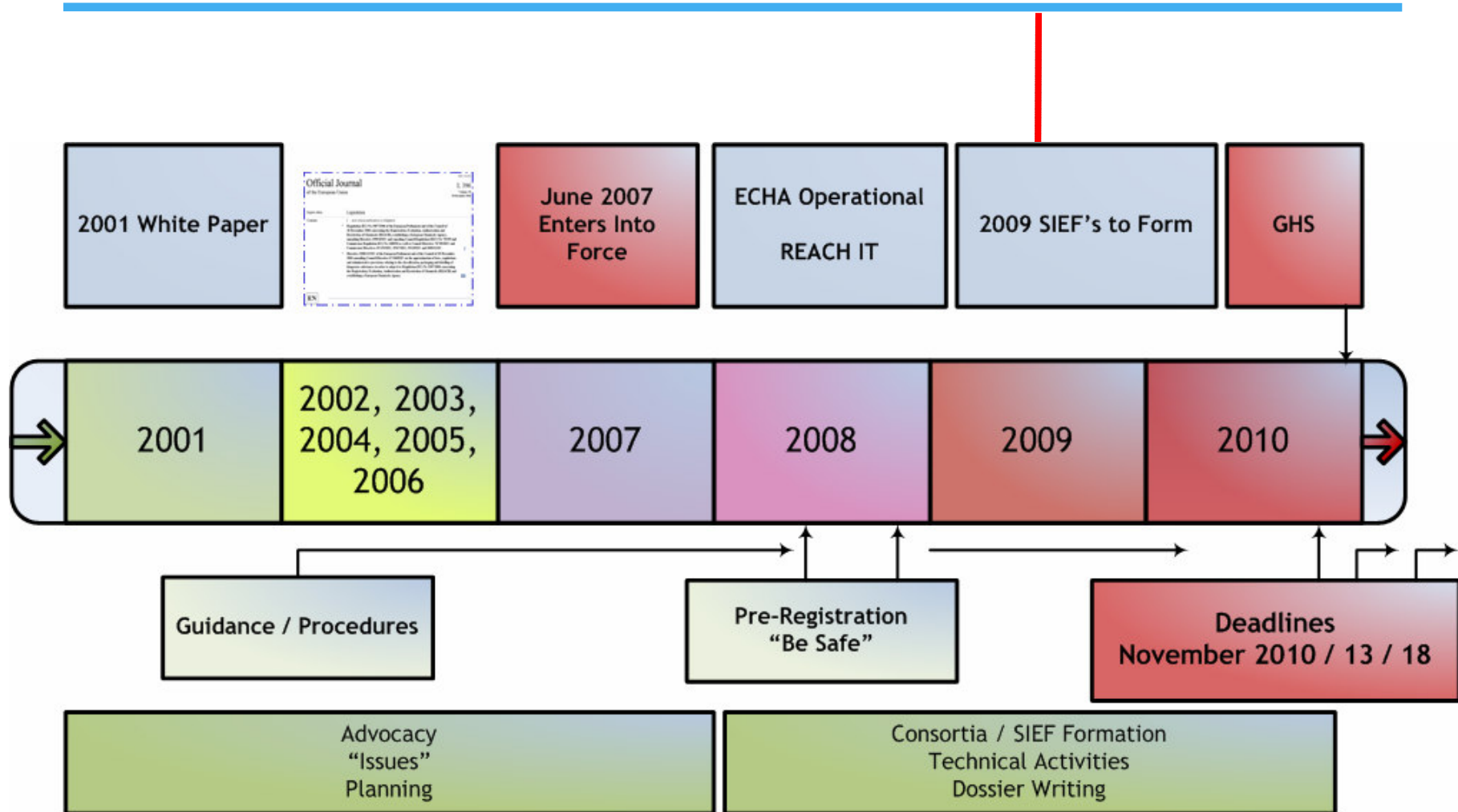




# REACH Tasks



# REACH Timeline



# REACH: Q3 2009 View

---

## Expected / Planned

- **>30,000 phase-in substances requiring registration under REACH by 2018**
- **26 March 2009 - 146,333 pre-SIEFs**
- **SFFs or Consortia would facilitate the SIEF's work**
- **Manageable sized SIEFs - known parties**
- **Time to organise and plan for completion of technical work**

## What has happened

- **> 146,000 substances pre-registered by 65,000 companies - (2,750,000 pre-registrations)**
- **14 July, only 797 SIEFs have active lead registrants**
- **30 March 2009 - 58% of pre-SIEFs with a 2010 deadline have "facilitators"**
  - **36% of all pre-SIEFs have "facilitators"**
- **Thousands of SIEF members – many with little apparent intention of registering**
- **Scope has paralysed activity for some**

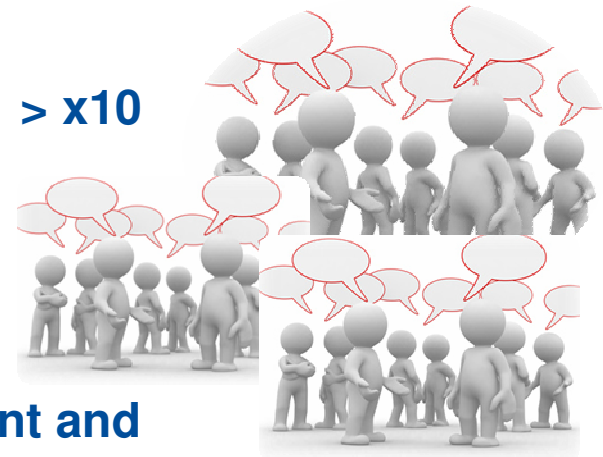
# SIEF Management and Strategy

---

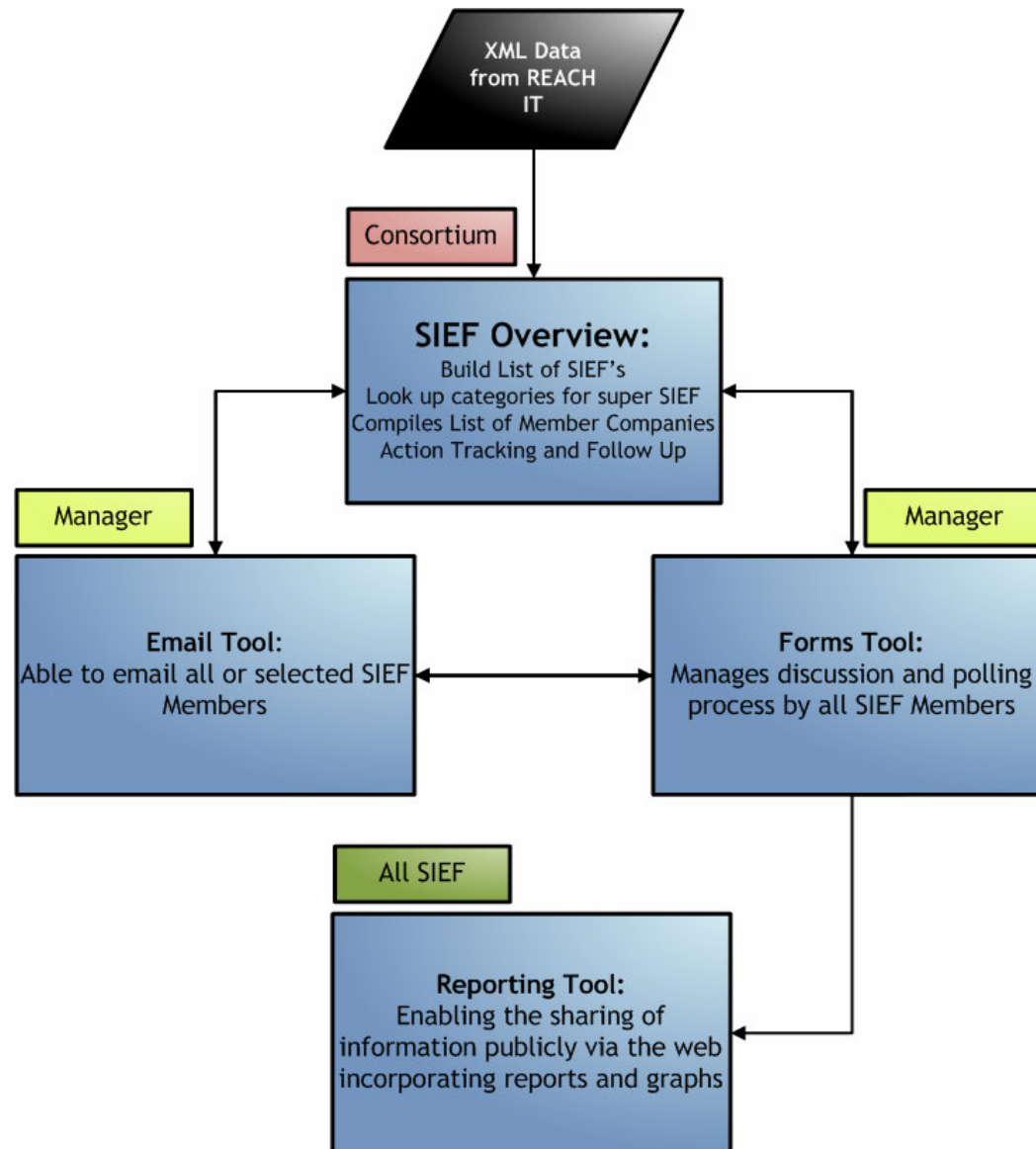
- **Thoughts 2005,6,7,..**
  - **Actions**
    - **Cooperative collaboration**
    - **Study review**
    - **Expert sessions**
      - **Classification and labelling**
  - **Tools**
    - **Discussion fora – chat rooms**
    - **Email communications**
  - **Major issue - how to get adequate company representation with available resources with many SIEFs to monitor**



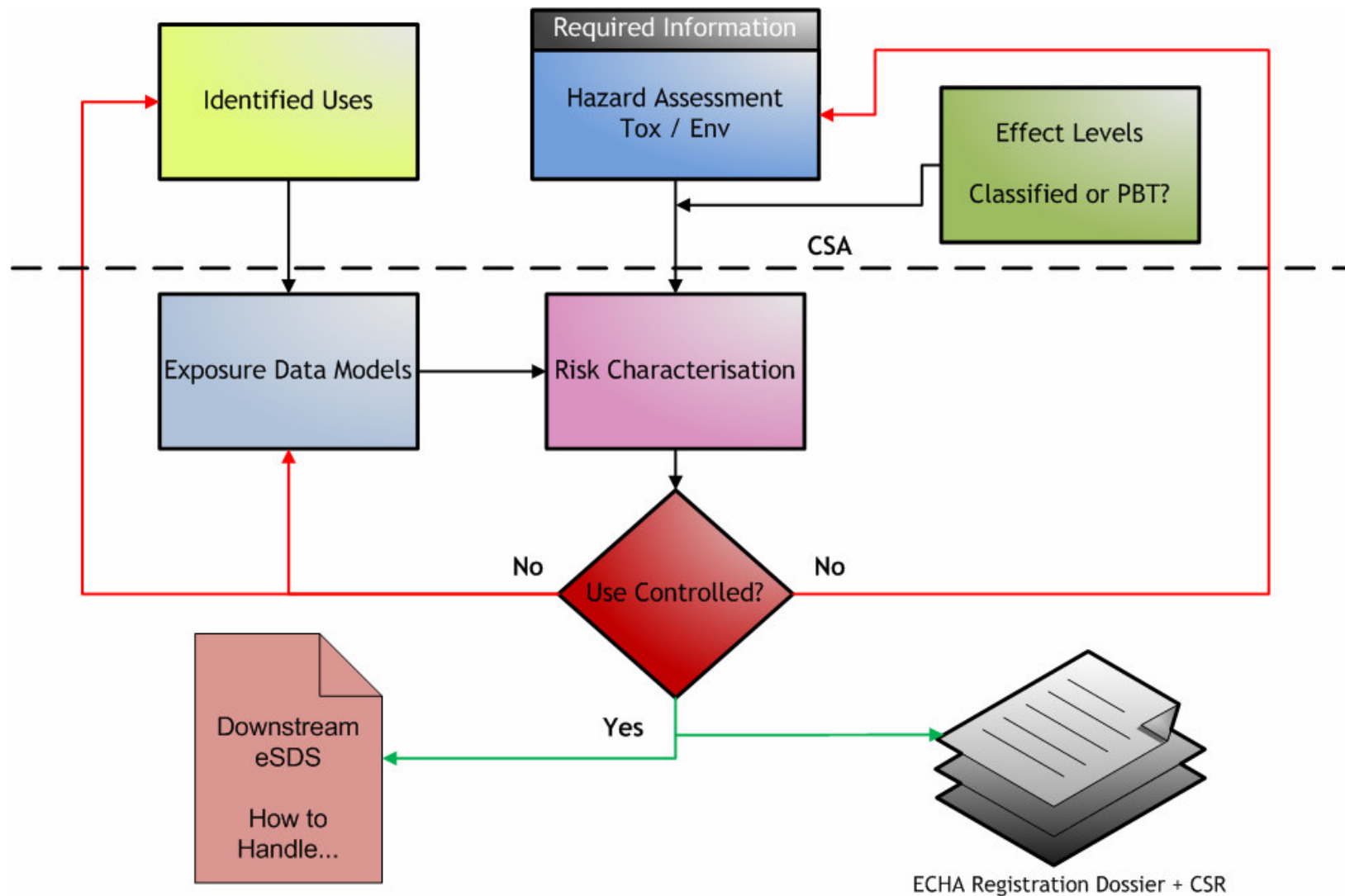
- **July 2009 Reality**
  - **Many more pre-registrants than anticipated > x10**
    - **Makes communication difficult**
    - **Meaningful dialogue almost impossible**
    - **Individual company voice diluted**
  - **Needs strong action to drive process**
  - **Leadership void in some SIEFs**
  - **Major issue - how to be seen to be compliant and “fair, transparent and non-discriminatory”**



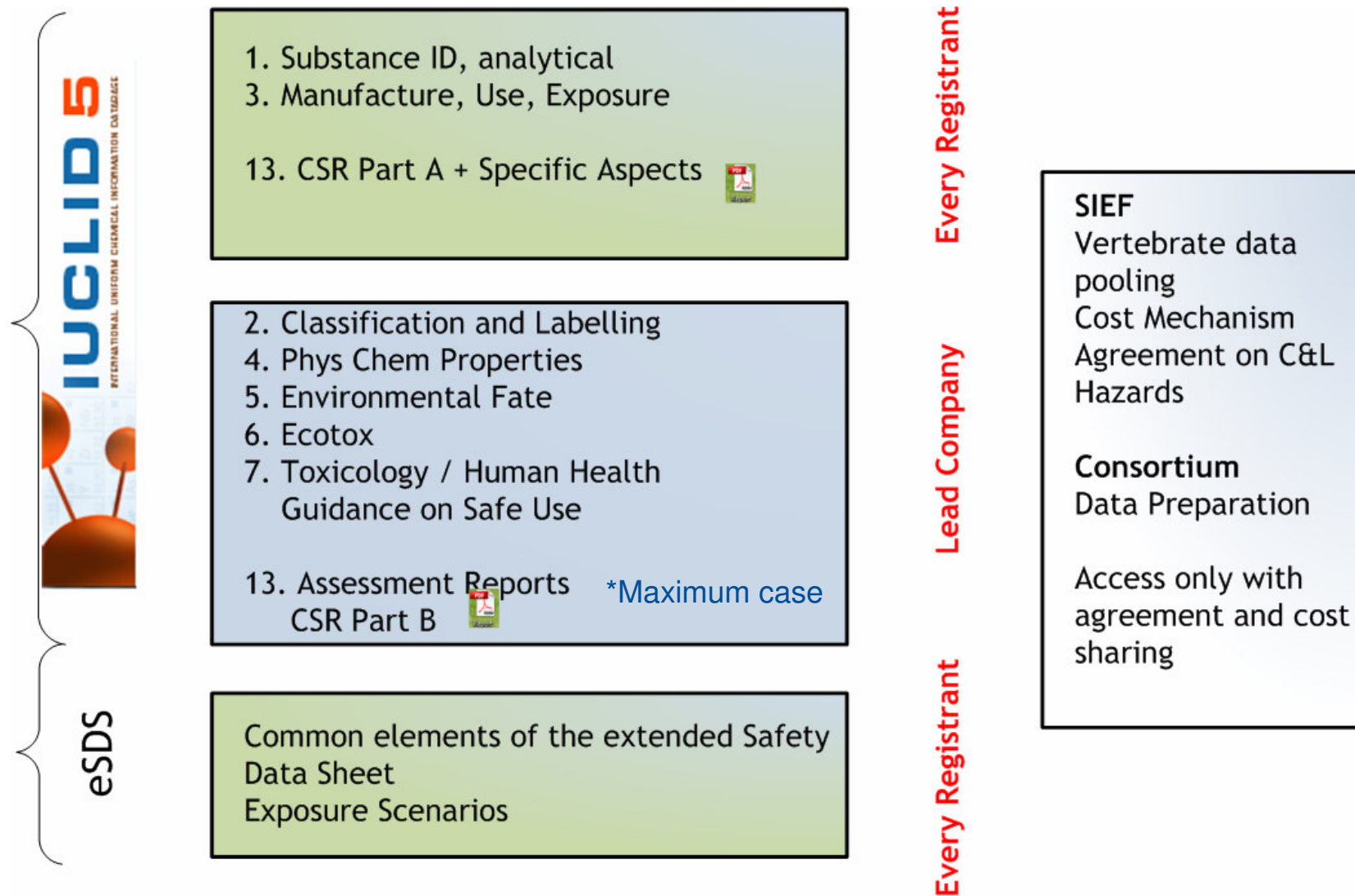
# REACHsuite Consortium / SIEF Module Overview



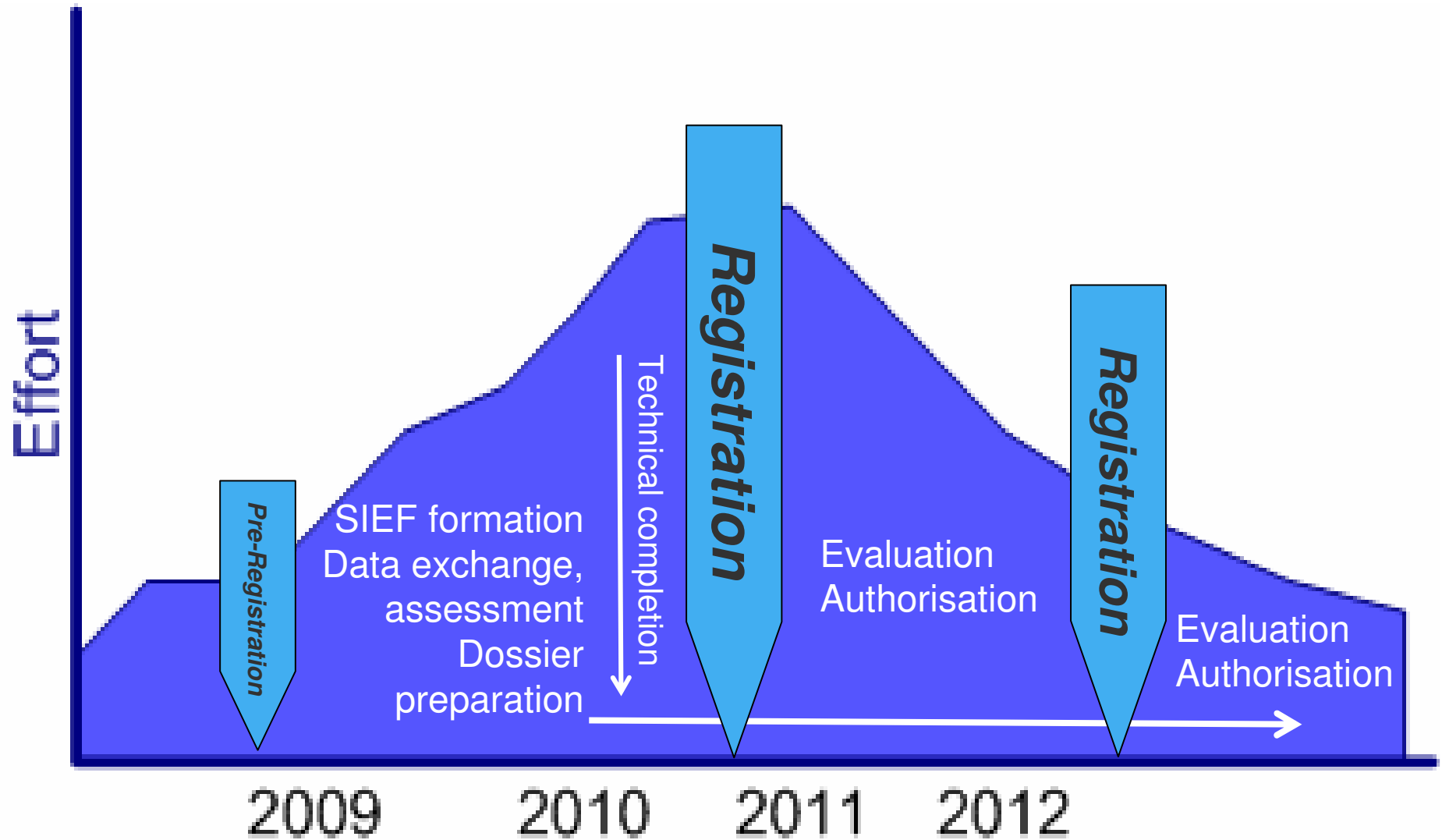
# The Basic REACH Process – per Substance



# The Registration Dossier – Who Will Submit What\*?



# REACH Registrant Activity – illustrative





# Are substances on track for registration?

---

- **For your Critical Chemistry – gauging progress**
  - Is there a Consortium or SIEF organised and active?
  - Is there a detailed plan on how the registration dossier will be compiled by competent resource?
    - Clear date and agreements?
  - Have you contacted or been contacted by committed SIEF members who manufacture or import?
    - Do they have credible plans?
- **If the answer is no – need to take practical steps towards the dossier preparation**
  - Willing to be the proactive industry leader?
    - Communicate with the SIEF members?
      - Initiate agreement
    - Develop detailed substance-specific planning
    - Identify the resources
    - Commission the technical work
      - What is required
    - Understand the uses .....
  - Build in time for iteration and inevitable confusion

# SIEF - why it is a critical initial step

---

- **Mandatory joint submission for hazard data by lead registrant**
- **Agreement on lead registrant - no appointment rules**
  - **Tasks of lead registrant**
    - Identify other registrants
    - Submit joint dossier, pay registration fee, and communicate registration number to other registrants
    - Request confidential treatment of data
    - Update joint dossier and pay fee
- **Facilitate common positions on classification and labelling**
- **Ensure that non-animal approaches between relevant substances are used to the full - e.g. categories (cost impact)**
- **Opting out is problematical**
  - **Reasons**
    - “Disproportionate” cost, protect confidentiality, disagreement with data selection by lead registrant
  - **Penalty**
    - Increased registration fees, prioritisation of the review

## Introduction - Hunton & Williams

---

- **Leader in EU chemical regulatory area**
- **Specific and deep REACH experience, including consortium agreements**
- **REACH Team: cross-office, client-focused, industry-experience, including in-house**
- **Regulatory, administrative, corporate, intellectual property, and antitrust expertise**
- **Experience with managing large industry groups**
- **Experience with organizing and establishing large REACH consortium (Lower Olefins & Aromatics Consortium), making it operational (rules and procedures, cost sharing rules for categories, accession of new members, IT contracts, etc.), and assisting it in “complying with REACH the smart way”**

# REACH Challenges and Solutions - Legal

---

- **Data and cost sharing** in respect of both existing data and new data required under REACH
  - REACH rules (law and guidance)
  - Contractual arrangements, ownership, etc.
- **Protection of Confidential Data**
  - Verification of substance identity may involve disclosure of CBI (sources of raw materials, production processes, etc.), in particular in case of UVCB substances
  - Trust arrangements
- Form or join a **Consortium?**
  - Understanding Consortium's rules and letters of access implications (relative costs, treatment of affiliates, categories, etc.)
- How to make **Consortium and SIEF work together** in compliance with law?
- **Competition law** issues

# REACH Challenges and Solutions - Legal

---

- **Cost sharing within Consortium and SIEFs**
  - Basis for cost sharing
    - Equal share
    - Proportional (volume, other?)
  - Distinguish various types of costs
    - Overhead
    - Technical, data access cost
  - Affiliates
    - Free or paid data access?
  - Substances in categories
    - For each substance registered?
  - Settlement
  - Discrepancies between Consortium and SIEF rules
  - Legal documentation and management

# REACH Challenges and Solutions - Legal

---

- **Data sharing**

- **Data rights acquisition**

- Exclusivity
    - Right to grant access to Consortium members and SIEF members
    - Cost

- **Granting data access**

- Scope (whole dossier, including CSR etc., or limited access)
    - REACH registration only
    - Access cost

- **Organizing and structuring data rights management**

- Accounting, tax, IP, liability, and other legal considerations
    - Decentralize activity or centralize?
    - Establish separate DRM vehicle

# Introduction – Baxter Jones, ICF

---

- **ICF International**
  - Large, diverse, and global
  - Broad range of REACH services, including scientific, program management, and IT
  - Over 200 scientific/technical staff in risk assessment sciences
  - Numerous active REACH engagements, including several large consortia and associations
- **Baxter Jones – 31 years consulting experience**
  - Environmental health scientist, with focus on risk assessment/risk modeling
  - Regulatory analysis and compliance
  - Government and industry clients

# REACH Challenges and Solutions - Technical

---

- **Challenge: Sheer amount of technical/scientific work**
  - **Volume of work: HIGH**
  - **Time available to complete work: SHORT**
  - **Learning curve: STEEP**
  
- **Challenge: Extensive scientific judgment required**
  - **Tens of thousands of pages of regulatory guidelines, but few black and white criteria to rely on – no cookbook, not even a recipe**
  - **Like all toxicology/risk assessment, remains highly judgment-based**
    - **Study reliability evaluation**
    - **Selection of key studies**
    - **Applying “read across”**
    - **Scope of exposure assessments**
  - **Thus, significant de novo scientific documentation required; not just blank-filling**



# REACH Challenges and Solutions - Technical

---

- **Challenge: Too much information, or too little**
  - Too much: time consuming, costly, scientific disagreements, possibly compensation disagreements
  - Too little: quicker and cheaper, but dependent on “read across” and other gap filling methods; more likely to end up with test plans
- **Challenge: Doing “just enough” science**
  - Must do all that’s necessary for completeness and adequacy
  - Doing too much costs more, and there’s not enough time anyway
- **Challenge: Addressing substances in multi-party groups**
  - Economies of scale don’t strictly apply, can be greater than linear increase in effort with more substances and more parties
    - Technical efforts roughly linear
    - Facilitation, coordination, interactions, reviews, and approvals related to technical efforts increase significantly

# REACH Solutions – Enabling tools

---

- **IT Enabling Tools**

REACHsuite 

- **Consortia / SIEF / Company management options**
- **Confidentiality maintained between working groups**
- **Communication tool – SIEF and partners – SIEF pages**
- **Polling tools – Downstream / SIEF / Consortia**
- **Document repository – liability mitigation**
- **Management of substances, Information Requirements data, Use**
- **Performance / progress indicators**



- **Effectively a mandatory tool**
- **Dossier preparation data storage**
- **Hosting options available for maximal data sharing during development**

# How to Meet the Late Challenges of REACH

---

- **A detailed costed business plan for every substance**
- **Take the initiative**
  - No one else cares about your business like you do!
- **Organise the SIEF**
  - Use the enabling tools to communicate and aid transparency of action and keep records
  - Develop a structure in which to work - gain rapid agreement on planning and costs
  - Document carefully
- **REACH is a technical regulation**
  - Engage competent technical resource - It is in short supply
  - Allow time for the technical people to deliver

**Try to avoid “issues” and concentrate on the deliverable – the Registration Dossier!**

# Summary / Conclusion

---

- **REACH is complex with crucial deadlines**
  - Procrastination is not an option
- **Establishing forms of cooperation - time-consuming but vital**
  - Legal structure and regulatory rules, documentation
- **REACH is a technical process**
  - Complex with scarce resources
    - Pre-registration was comparatively easy!
- **Preparing for registration is time-consuming and complex**
  
- **Today's Team – available to help you**
  - Deep relevant industry, regulatory and technical experience
- **Legal services via world class providers**
- **Technical capacity**
  - Meets or exceeds that of established players
    - Significant capacity in service organisations
    - Continuing ability for service provision on as needed on an as agreed basis
- **Resource management**
  - Virtual (web-based) communication

1 year, 4 months, 8 days to go

# Contact Information

---

- **ICF International**

- [www.icfi.com/REACH](http://www.icfi.com/REACH)
- Baxter Jones, [bjones@icfi.com](mailto:bjones@icfi.com), +1 703.934.3210
- Jay Hadley, [jhadley@icfi.com](mailto:jhadley@icfi.com), +1 703.934.3587

- **Hunton & Williams**

- [lbergkamp@hunton.com](mailto:lbergkamp@hunton.com)
- + 322 643 5800

- **Penman Consulting**

- [info@penmanconsulting.com](mailto:info@penmanconsulting.com)
- + 322 305 0698
- <http://www.reachsuite.com>

REACH suite 

# Questions?

---



22 July 2009

---

**Thank you for your time**



22 July 2009

**ICF**  
INTERNATIONAL®

HUNTON &  
WILLIAMS

**Penman**  
Consulting BVBA