

concaawe



## REACH – The Untold Story

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- ▶ Shaping the programme
  - ▶ Shifting targets
  - ▶ Need for project structure
- ▶ SIEF issues
  - ▶ License Agreements
  - ▶ Spoilers
- ▶ Moving targets
  - ▶ Guidance
  - ▶ IT issues
- ▶ Direct costs
- ▶ Personal cost
- ▶ Advice to Member Companies
  - ▶ Issue papers
  - ▶ Analytical information for registration
- ▶ Surprises yet to come.....

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- ▶ Technically sound and cost-effective programme based on our voluntary risk assessment programme. In the end, it was a different paradigm...resulting in an initial underestimation of the work involved
- ▶ Shifting targets and expectations
  - ▶ Groups to Categories
  - ▶ Back to a first principles review of available data
  - ▶ Information re-packaged to satisfy the IUCLID5 structure
- ▶ Needed to develop new methodologies and tools for
  - ▶ Derivation of DNELs
  - ▶ Practical application of (unproven) Use Descriptor System
  - ▶ Human health exposure assessment
  - ▶ Environmental risk assessment (PETRORISK)
- ▶ Need for project structure
  - ▶ Need to secure commitment of resources to deal with technical and non-technical issues (but the task continued to evolve)
  - ▶ Expert input/review was required in particular time windows, with little space for slippage

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- ▶ No legal basis for SIEFs, but legal obligations
- ▶ Competition law concerns
- ▶ License Agreements
  - ▶ Member Companies use of data
  - ▶ Licensees use of data
  - ▶ Requirements for Lead Registrants
  - ▶ Requirements for all members of SIEF
- ▶ SIEF communication
  - ▶ How, what and when?
- ▶ Token control
- ▶ Invoicing processes
- ▶ Process for secure file sharing
- ▶ Predatory Only Representatives/Facilitators, Spammers and Opportunists
- ▶ Working with other SIEFs, especially LOA

**Costs of running the SIEFs over the two years up to first registrations is 1.5M€**



- ▶ Guidance
  - ▶ Involvement in Partner Expert Groups (more difficult as experts focussed on registration)
  - ▶ Stakeholder consultation processes
  - ▶ Late arrival of essential guidance
  - ▶ Update and re-issue of existing Guidance
- ▶ Moratorium on publication of new guidance agreed in Directors' Contact Group for May 2010, but.....key decisions on dossiers had to be made by the end of 2009 to allow for completion on time
- ▶ IT issues (ongoing)
  - ▶ Changing IUCLID5 and REACH-IT requirements
  - ▶ New versions of the software (and the TCC)
  - ▶ Guidance notes
- ▶ Hardware requirements (ongoing)



- ▶ Data costs and tool development
  - ▶ CONCAWE joint programmes (shared at no cost)
  - ▶ API joint programmes (shared at no cost)
  - ▶ Companies (shared at no cost)
  - ▶ Third parties and licensees
- ▶ Specialist contractors
  - ▶ Quality help at a premium and over-stretched
  - ▶ Charlatans
- ▶ Contractors
  - ▶ Quality help at a premium (and over-stretched)

**The total cost of the project in CONCAWE has been estimated at 41M€**

- ▶ Analysis of samples for each legal entity
- ▶ Registration fees

**Approximately 4700 petroleum substance registrations were completed in 2010  
This represents approximately 20% of all the registrations made**



- ▶ Member companies sweat equity.....limited number of member companies able to support the expert groups
- ▶ Secretariat effort supplemented and re-focussed to ensure delivery on time
- ▶ Man hours (telecons, meetings, travelling, evenings, weekends)
- ▶ Delivery of key project milestones on time to prevent slippage in the programme
  - ▶ Compression of time-lines
- ▶ Late-night emails, sleepless nights, grey hair.....

**An estimated 6700 person-days of effort (Secretariat and Member Company) were directed towards the work in CONCAWE over the five years of the project (~ 30 person-years of effort)**

- ▶ The 'day job' continued (including preparing own companies for registration, preparing and submitting registration dossiers, etc.)



- ▶ In addition to the common parts of registration dossiers covering 570 petroleum substances across 21 Categories.....
- ▶ New CONCAWE members
  - ▶ REACH training and awareness
  - ▶ PPMG as information exchange
- ▶ Issue papers
  - ▶ Various trading issues
  - ▶ SCC for intermediates
  - ▶ Exemptions
- ▶ Analytical information for registration
- ▶ Updated advice on harmonised hazard classification (DSD and CLP)
- ▶ Advice on registration

AND CLP deadlines were superimposed on the REACH deadlines





- ▶ Unproven/untested concepts – road-testing of the Use Descriptor System has only just started
- ▶ Communication in the supply chain (supported uses, use descriptors, risk management measures) is really only just beginning
- ▶ The eSDS as an effective means to communicate information?
  - ▶ new concepts (DNELs, DMELs, SPERCs, PNECS, RMM, ES, Msafe, etc)
  - ▶ 100+ pages
- ▶ The importance of assumptions.....in exposures and RMMS have yet to become apparent. The consequences of apparently inconsequential decisions will become clear over time.....the devil is in the detail
- ▶ Dossier Evaluation.....?



- ▶ Every aspect of developing the registration materials and completing registrations proved to be more complicated and more time-consuming than originally envisaged
  - ▶ Most Downstream Users are only now beginning to think about what REACH may mean for them - as the first wave of eSDS arrive
  - ▶ The guidance still keeps on coming, with an expectation that existing registration dossiers will be updated to keep them aligned
  - ▶ Stakeholder processes are not working well – decision-making processes are not clearly inclusive or transparent
  - ▶ Is there corporate/institutional memory at ECHA (to avoid re-visiting issues that have already been decided)? The signs are not encouraging...
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- ▶ This is only the end of the beginning. The next steps.....

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