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Experiences Arising from the Development of CSAs/ESs for Petroleum Substances

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Outline

- Background to CONCAWE's 2008/2010 REACH activities
- Application of GESs to petroleum products
- Areas for refinement and improvement
- Lessons for 2013 Registrations
- Summary

Overview of CONCAWE REACH Activities

- **Some basic data …**

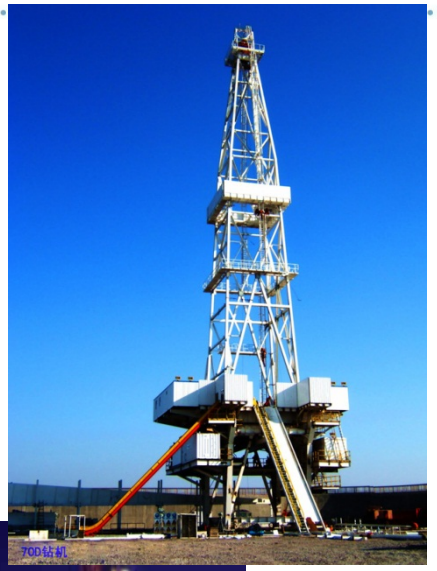
- The CONCAWE managed consortium/SIEFs covered ..
  - 202 substances in total
  - 21 categories
  - 491 companies in the consortium and SIEFs
  - Led to the submission of 4241 registrations in 2010
  - And where each CSR typically amounted to 350+ pages
  - And cited references averaged 180+ per CSR/IUCLID

Development of CSAs for PPs

- Desire to yield CSAs/ESs consistent in form and content to those being developed in related supply chains e.g. petrochemicals
- Adopted ESVOC GESs as base case with one eye on ..
  - Adequacy of solvent-based mappings/descriptions for solvent-like products i.e. petroleum substances
  - Adequacy of TRA-based estimates for different 'exposure realities' e.g. mists; fumes
    - And available exposure data for petroleum substances
  - Adequacy of available ESVOC/BDI phrases for specifics of petroleum products/uses
  - The fact that these substances are widely imported and traded
    - SIEF sizes typically consisting of 500-2000 members
- We are an industry that is already heavily regulated
  - IPPC; Seveso; VOC Directive; Carcinogens Directive; etc.
  - Need to ensure the CSA outcomes also align with these

Adequacy of Available ESVOC GESs

Which ones worked ?



- Uses in coatings
- Metalworking fluids
- Oil and gas exploration and production
- Manufacture
- Rubber manufacture
- Etc ..

Adequacy of Available ESVOC GESs

Which ones needed to be developed or further refined ?

- **Comparatively few!**

- Road and construction
- Roofing activities
- Shingles manufacture
- Roofing membranes (hot and cold)

Reasons for Updating

- Conflicts in the choice and allocation of use descriptors
  - The lack of clarity/specificity in the ChR12 UDs led to multiple interpretations and 'low value' discussions
  - The work undertaken by ESIG helped tremendously in brokering consensus elsewhere
- Terminology used to describe uses ..
  - The description of some contributing scenarios required 'refinement' to accommodate the language of PPs
- Some GESs were too broadly described to adequately cover the uses of petroleum substances
  - Especially consumers, particularly fuels
- The TRA exposure estimates did not always match REACH with real life experiences
  - 'Reality checks' were necessary to account for issues such as flammability, aerosols; fumes; etc.
  - Demands access to suitably skilled technical resources

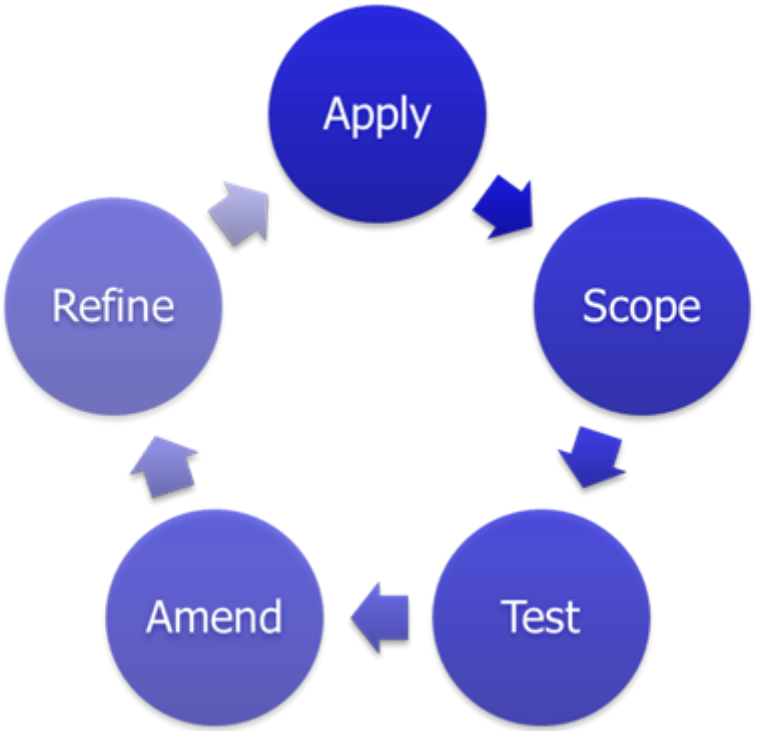
Adapting the GESs

Issue	Solution
Some ESIG GES descriptions insufficiently 'detailed' for some petroleum substances	Affected GESs extended to include sufficient detail to adequately describe use and characteristics of exposure control strategies
Common refining control strategies not included in TRA	Refinery-specific OCs and RMMs identified and justified consistent with TRA expectations e.g. vapour recovery; drum pumps; closed lock systems; remote operations, etc.
TRA based predictions do not cover mists and fumes	ESIG CSA framework extended to address potential for mists/fumes based on relevant PROCs e.g. 6,7,11, 17, 18
Inability to derive DNELs for certain endpoints	Development of rationale for the choice and application of suitable qualitative OCs/RMMs for relevant endpoints

Key Learnings

- Recognise that many of the tools come with their own 'domain of reliability'
  - If your chemistry set or circumstances of use lie outside, then solutions need to be identified if the CSA is to be complete
  - These solutions take time to develop and validate
  - The solutions should be available for others in order to facilitate consistency within and across supply chains
  - The limitations of the available tools are not always explicit.
  - But despite the constraints, the efficiencies delivered from the use of GESs are enormous
  - Avoid unnecessary discussions on those things where consensus already exists
  - Focus on the things that matter
  - ❖ **Allow adequate time for planning within Consortia**

Planning for the Unforeseen



- Technical solutions do not become apparent or available instantaneously
- Incorporate time to scope, test and apply
- CONCAWE's experience is that this can take 3-6 months of intensive effort.

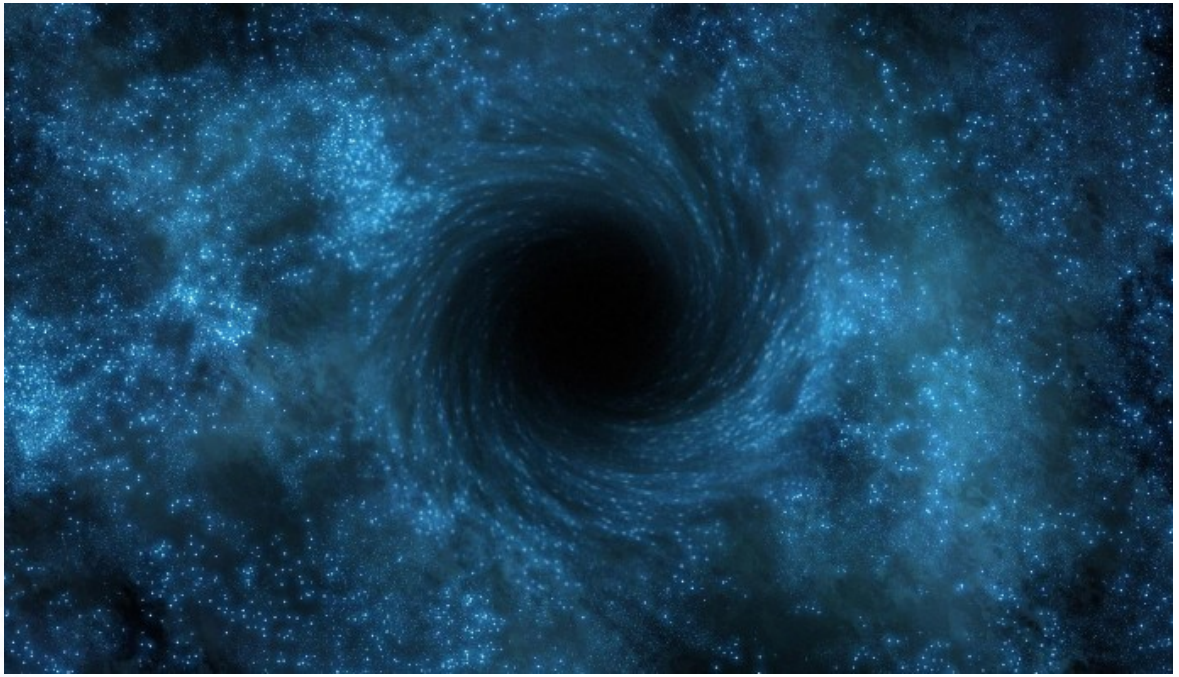
ESs and the Environment

- Petroleum substances typically comprise many thousands of individual hydrocarbon constituents (complex UVCB substances)
- Models for predicting environmental exposure (e.g. EUSES) are intended for simple substances
- The CHESAR tool cannot be used for the risk assessment of UVCB petroleum substances
- CONCAWE proposed the Hydrocarbon Block Method, developing PETRORISK to undertake risk assessments for REACH
- PETRORISK calculates the sum of the risks posed by the components of the UVCB substance for each ES, based on
  - detailed composition
  - defined regional tonnage estimates for each ES
  - estimated release fractions for each ES

ESs and the Environment

- Release fractions are derived from ERCs, A/B tables, SpERCS and site specific data (on emissions during manufacture)
- ERCs often represent very conservative estimates of the release fraction – SpERCS allow use of existing knowledge on environmental releases
  - banding of release estimates by volatility class for emissions to air
  - banding of release estimates by water solubility class for emissions to water
- The rationale outlining the basis for the SpERCs is included in factsheets, published on the ESIG website
- PETRORISK outputs via a template allowing direct input to the CSR (and subsequent inclusion in the SDS ES annex)

Contribution of the SIEF



Although we anticipated and planned for ‘SIEF churn’, our experiences were that

- The SIEFs made no meaningful contribution to either the processes for describing uses or characterising risks
- The primary concern of the SIEF was that letters of access were delivered on time (and cheaply)

Lessons for 2013 and Beyond

- The CSA/ES expectations of REACH are straightforward

BUT

- Be proactive. Allow adequate time for planning and discussion
  - It is not the technical tasks that take the time but the need to consult/engage/educate representative DU groups
- Be prepared to learn from and adapt the lessons of others
  - REACH is not about the pursuit of perfect. It is about demonstrating and communicating 'safe use'
  - CSAs/ESs need to be 'fit for purpose'
- Recognise that the Technical Guidance and supporting tools do not cover everything
  - Be mindful of the need to be resourceful in terms of solutions
- All the technical solutions derived from within companies
  - Consultants did not add the value we'd hoped for
  - ✓ Be confident in your own abilities

Summary

- We successfully developed CSAs/ESs for all classified petroleum (UVCB) product categories
- The GESs offer enormous efficiency gains for those sectors who are able to apply them
  - But they may require adaptation in some instances
- We are continuing to work topics
  - REACH has highlighted areas where our understandings are more developed than in others
  - We will be documenting the rationale for our approach and the basis for our assumptions
- We are continuing to dialogue with customer and their trade groups
  - Ext-SDSs need explanation and supporting change management processes for those that use them
- ❖ We are not complacent : we have no misconceptions that new and unforeseen issues may still arise during dossier/substance evaluation