

# How to check compliance with REACH environmental exposure assessments (for petroleum products)

Miriam León Paumen  
ExxonMobil Biomedical Sciences  
DUCG Workshop, Brussels  
October 21 2011

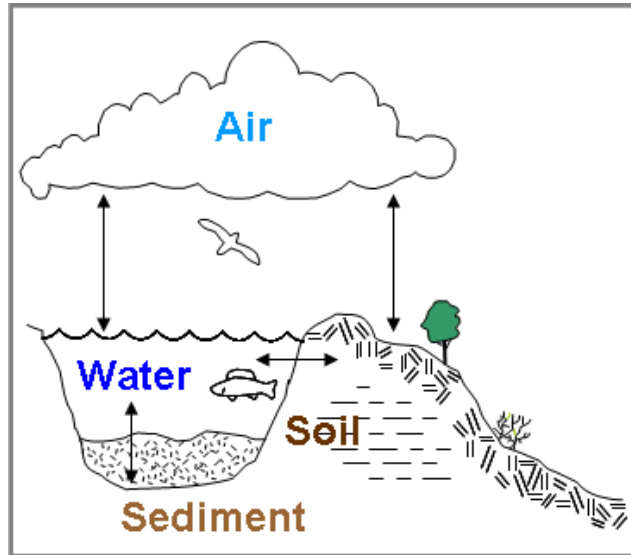


# Environmental risk assessments

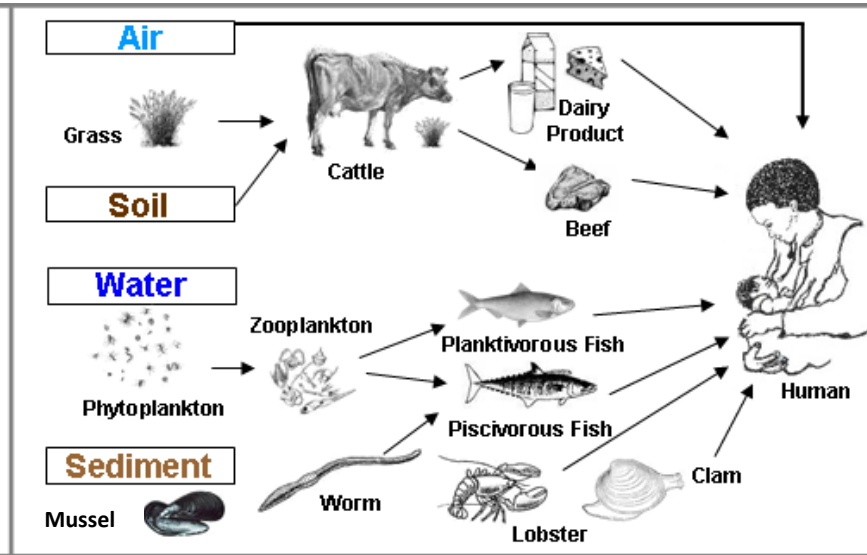
**PRODUCT**



**Environmental distribution**



**Exposure pathways**



**REACH: Exposure Scenarios**

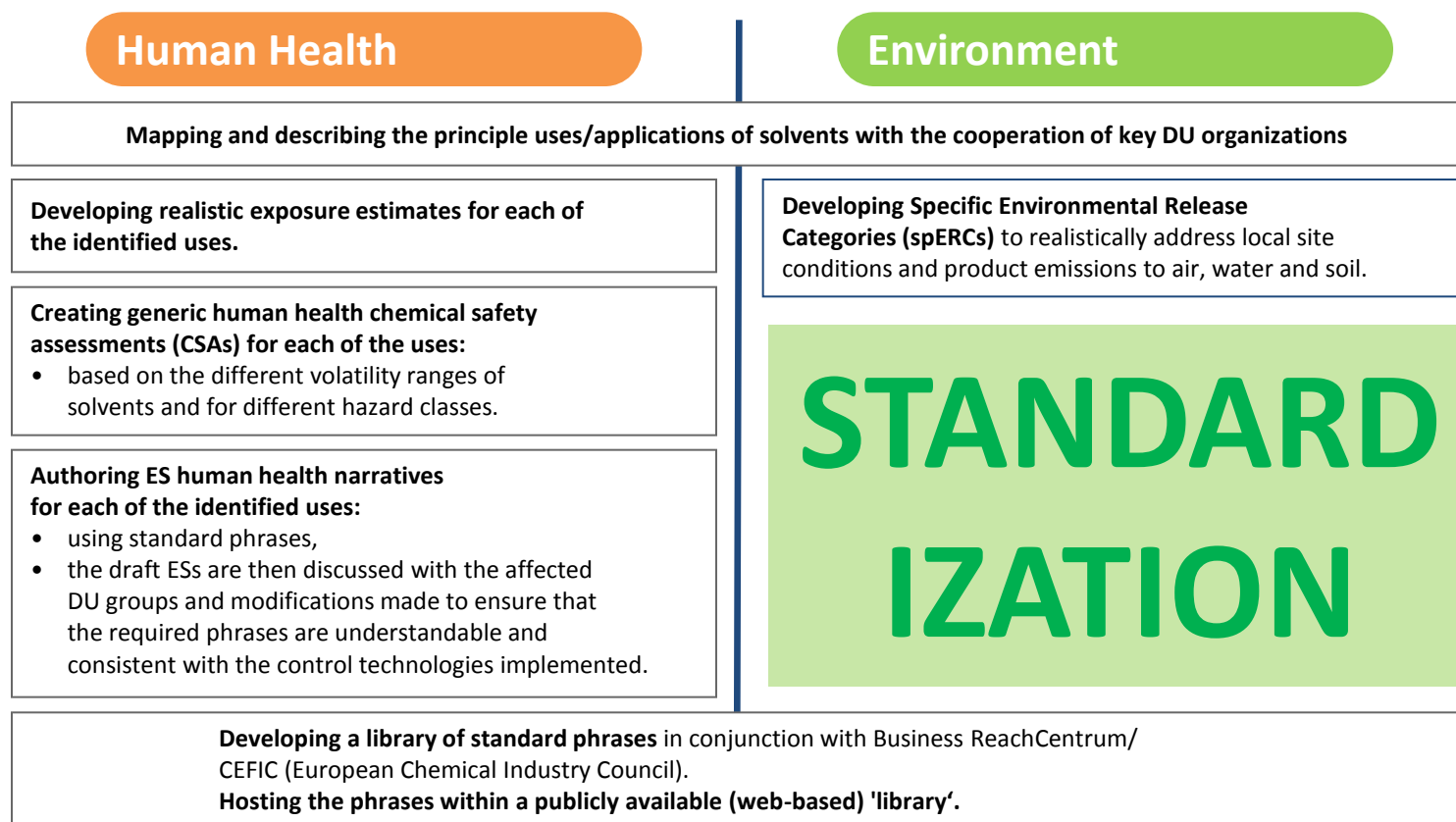
**RISK<sub>2</sub>**

# Environmental Exposure Scenarios

- Environmental ES describes the **assumptions** and **outcome** of a risk assessment for a substance use in a specific sector (e.g. Industrial use of coatings)
  - REACH regulation requires an exposure assessment to be performed for each environmental compartment and exposure route
  - For classified substances only
- REACH exposure assessments are performed in a standardized way, following REACH guidance
  - Follow Generic Exposure Scenario (GES) principles
  - Use (Specific) Environmental Release Categories (ERCS and SpERCs) to define **inputs** for the exposure assessment
  - Express **outputs** of exposure assessment in standard phrases
- Risk assessment is performed at two levels
  - Regional (calculation of background levels for local assessment)
  - **Local** (site scale, relevant scale for downstream users)

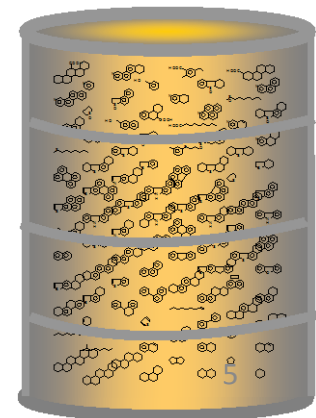
# What are GESs?

- The Generic Exposure Scenarios (GESs) represent a family of work activities / substances
  - Human Health: Contributing scenarios
  - Environment: Operating Conditions (OCs) and Emission Factors
- They aim to ease the burden of REACH by:

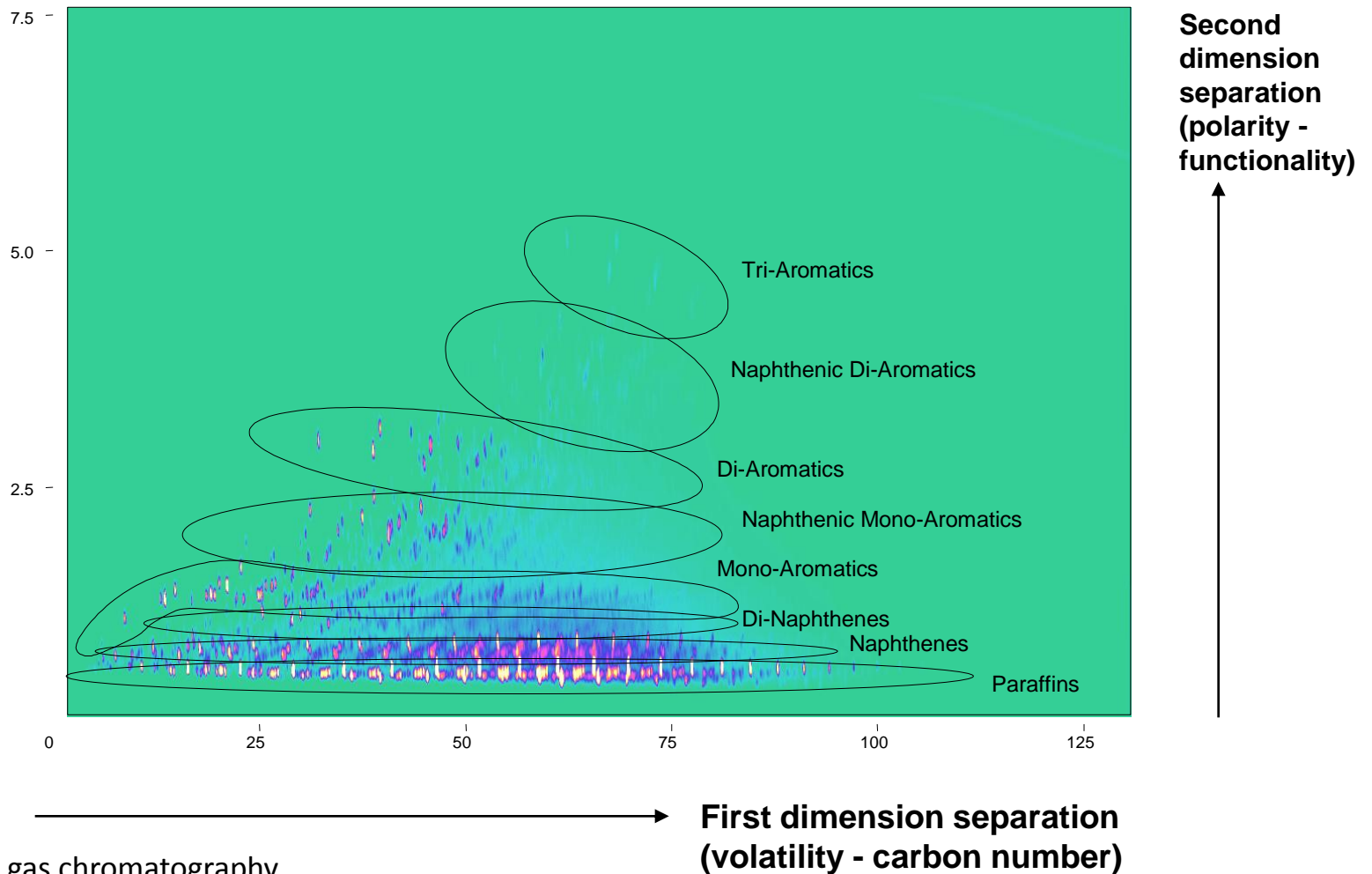


# REACH ES example: petroleum substances

- Derived from crude oils
- Not intentional mixtures of specific chemicals
- Not defined in terms of individual constituents
- Contain numerous structures
  - related isomers of different hydrocarbon classes with undefined & variable composition, i.e. they are UVCBs
- Produced according to technical performance specifications
- Typically defined by refining process, distillation range, carbon number range, viscosity and hydrocarbon classes, etc.
- Petroleum substances are grouped together into major product categories
  - e.g. kerosines, gas oils, base oils, aromatic extracts, etc.



# GCxGC\* plot of a middle distillate sample



\* Two dimensional gas chromatography

DUCC Workshop, Brussels, October 21 2011

# Petroleum substances REACH ESs

- Hydrocarbon block methodology (HBM)
  - Originally proposed by CONCAWE
    - Complex substance is divided into “pseudo-components”, constituents with known physico-chemical, fate and hazard properties, stored in **CONCAWE library**
    - PECs and PNECs for individual constituents are determined
    - Overall substance risk is assessed by summing PEC/PNEC ratios across constituents
    - Accepted by regulators, incorporated in REACH guidance
- HBM implementation: PETRORISK tool
  - Based on EUSES
  - Specific features to make hydrocarbon UVCB risk assessment possible, e.g. composition matrix

# Assumptions/input risk assessment PSs

- Environmental Release Categories (ERCs) and Sp(ecific)ERCs

	ERC
<b>Emission Estimation</b>	Standardized
<b>Defaults</b>	Worst case
<b>Risk Management Measures</b>	Not included
<b>Responsibility</b>	ECHA

Specific ERC (SpERC)
Standardized
Good practice
Considered
Sector Groups/Trade Associations

- Industry evaluation of ERCs
  - Very conservative emission estimate (initial screening)
  - Refinement often required
  - Applicable to manufacturers and downstream users



# Assumptions/input risk assessment PSs

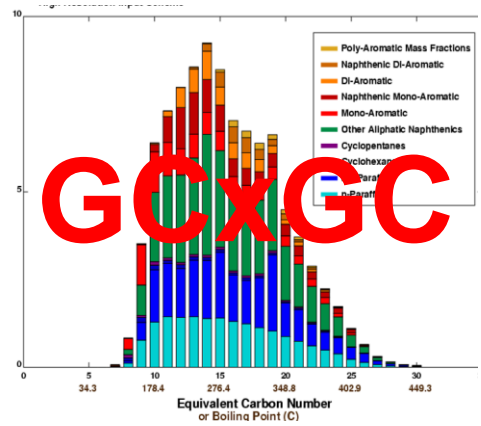
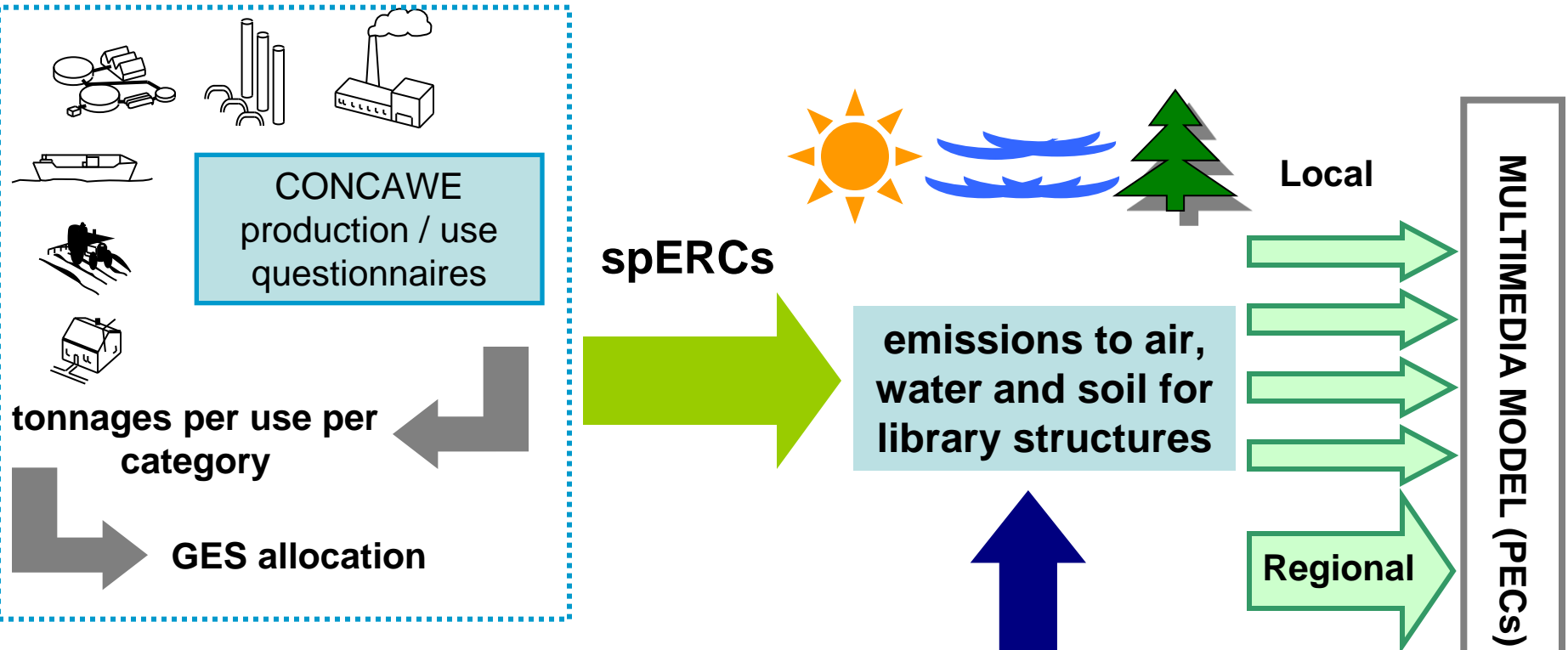
- **SpERCs** serve as instruments for describing environmental releases in GESs
  - Incorporate industry sector knowledge on main processes / typical RMMs
  - Refine release factors based on available data (ERCs, OECD Emission Scenario Documents (ESDs), Sector questionnaires, Part 4 of the EU TGD)
  - Differentiate industrial & wide dispersive uses (Professional & Consumer)
  - Distinguish solvent-borne & water-borne uses
  - Utilize CEFIC RMM library to define default RMM for air
  - Apply Domestic WWTP as default RMM for water
- SpERCs available for all CONCAWE relevant GESs
- Alignment ongoing between Sector Groups/Trade Associations
- Justification documented in Factsheets
  - <http://www.esig.org/en/regulatory-information/reach/ges-library/ges-spercs-2>
- Cefic has published a library of spERCs for many sector associations

# Example: 'Solvent-borne' SpERCs

- Set of SpERCs for 'Uses in Coatings' & 'Uses in Cleaning Agents'

GES Title	Area of Application / UD	max site tonnage t/day	Number of emission days	release to air before RMM (%)	efficiency of air emission controls (%)	release to air (%)	release to wastewater (%)	release to soil (%)
<b>Identified Solvent</b>								
Uses in Coatings	Industrial (SU3)	50	300	95.0	98.0	1.9	f(WS) WS < 1mg/L = 0.002 WS 1-10 mg/l = 0.007 WS 10-100 mg/L = 0.07 WS 100-1000 mg/L = 0.7 WS > 1000 mg/l = 2	0.0
	Professional (SU22)	EU Tonnage for use x 0.1 x 0.0005	365	99.0	N/A	99.0	0.0	1.0
	Consumer (SU21)	EU Tonnage for use x 0.1 x 0.0005	365	99.0	N/A	99.0	0.0	1.0
Use in Cleaning Agents	Industrial (SU3)	5.0	100	95.0	95.0	4.8	f(WS) WS < 1mg/L = 0.00001 WS 1-10 mg/l = 0.00003 WS 10-100 mg/L = 0.0003 WS 100-1000 mg/L = 0.003 WS > 1000 mg/l = 0.01	0.00
	Professional (SU22)	EU Tonnage for use x 0.1 x 0.0005	365	99.0	N/A	99.0	0.0	1.0
	Consumer (SU21)	EU Tonnage for use x 0.1 x 0.0005	365	99.0	N/A	99.0	0.0	1.0

# Estimating emissions for PSs



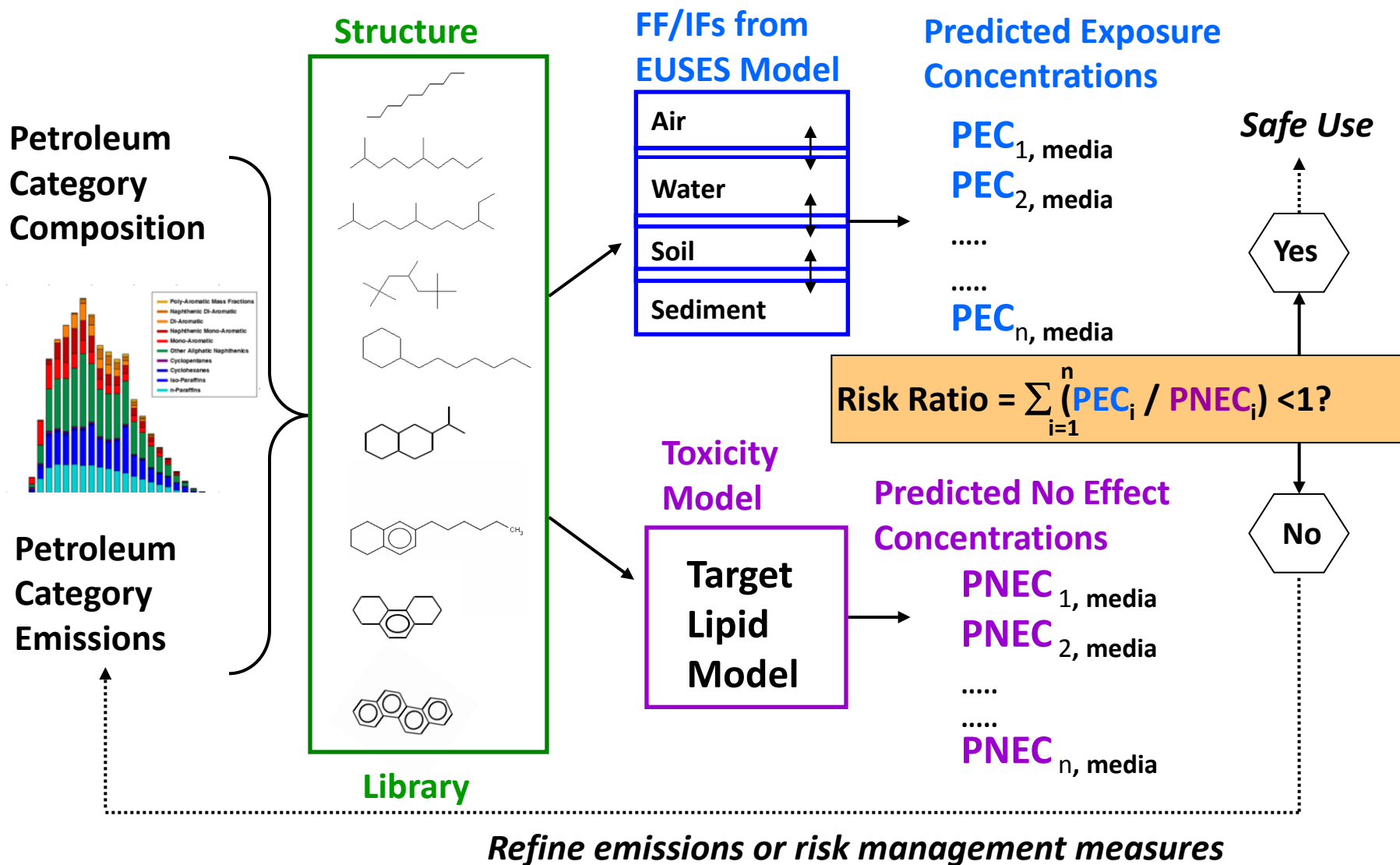
**map to CONCAWE library**

**HC COMPONENTS**

**allocate components to environmental compartments using simulated composition / Raoult's Law**

*approach conservative since category emissions applied to substance registrations*

# Estimating risk for PSs: PETRORISK



# PETRORISK local ESs worksheet

Row	Column	1	2	3	4	5	6	7	8	9
1	2	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9
3	3	1.1E+07	1.3E+05	1.1E+07	1.1E+07	1.0E+02	1.0E+02	1.1E+07	3.3E+05	2.2E+04
4	4	5.2E-02	1.2E-01	2.0E-03	2.6E-03	1.0E+00	5.0E-04	1.4E-01	5.0E-04	5.0E-04
5	5	6.0E+05	1.5E+04	2.3E+04	3.0E+04	1.0E+02	5.0E-02	1.5E+06	1.7E+02	1.1E+01
6	6	2.0E+06	5.0E+04	7.7E+04	1.0E+05	5.0E+03	1.4E-01	5.0E+06	4.6E+02	3.0E+01
7	7	300	300	300	300	20	365	300	365	365
8	8	3.0E-06	1.0E-05	1.0E-07	5.0E-06	2.0E-05	1.0E-02	4.4E-07	1.0E-05	1.0E-02
9	9	1.0E-04	1.0E-05	1.0E-04	2.2E-03	3.8E-01	3.8E-01	7.0E-04	1.0E-04	3.5E-01
10	10	10	10	10	10	10	10	10	10	10
11	11	100	100	100	100	100	100	100	100	100
12	12	90.0	80.0	90.0	0.0	90.0	0.0	95.0	0.0	0.0
13	13	oral exposure - excluding inhalation	freshwater sediment	oral exposure - excluding inhalation	inhalation	oral exposure - excluding inhalation	oral exposure - excluding inhalation	freshwater sediment	oral exposure - excluding inhalation	oral exposure - excluding inhalation
14	14	Yes	Yes	No	Yes	No	No	Yes	No	Yes
15	15	85.9	54.0	0.0	54.0	0.0	0.0	87.7	0.0	30.2
16	16	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
17	17	88.8	88.8	88.8	88.8	88.8	88.8	88.8	88.8	88.8
18	18	88.8	88.8	88.8	88.8	88.8	88.8	88.8	88.8	88.8
19	19	2.3E+06	1.9E+05	3.8E+05	1.1E+05	1.7E+04	7.0E-01	5.2E+06	2.3E+03	1.1E+02
20	20	3.4E+01	3.5E+00	3.1E+00	1.6E+02	5.5E-03	2.7E+00	1.3E+01	3.1E+00	6.0E+02
21	21	8.4E+01	3.1E+00	2.8E+00	1.4E+02	4.9E-03	2.4E+00	1.2E+01	8.1E+00	5.3E+02
22	22	3.3E+02	1.4E+00	3.2E+02	6.8E+04	2.7E+01	2.7E+02	1.1E+03	3.3E+01	5.7E+04

CSR

- Output parameters: risk driving compartment, required WWTP removal efficiency (RRE), “safe” tonnage
  - Parameters incorporated in **cefic / CONCAWE CSR template (and ext –SDS)**

# Standard (GES) - ext-SDSs

- SDSs tailored to specific uses based on 2009 customer dialogue
- The 'identified uses' are described using harmonised Use Descriptors:
  - PROCs, PCs, ERCs
- The RMMs and OCs are communicated in the form of standard phrases in a standard template
- Any cited OCs/RMMs have been 'benchmarked' against industry practice

# Example Section 2 - 2.2 Control of environmental exposure

<b>Section 2.2 Control of environmental exposure</b>
<b>Product characteristics</b>
Predominantly hydrophobic. Substance is complex UVCB.
<b>Duration, frequency and amount</b>
Annual site tonnage (tonnes/year): 100 tons/yr Continuous release. Emission Days (days/year): 20 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 0.42 Maximum daily site tonnage (kg/d): 5000 kg / day Regional use tonnage (tonnes/year): 240 tons/yr
<b>Environmental factors not influenced by risk management</b>
Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100
<b>Other given operational conditions affecting environmental exposure</b>
Release fraction to air from process: 0.3 Release fraction to soil from process (regional only): 0 Release fraction to wastewater from process: 3e-006
<b>Technical conditions and measures at process level (source) to prevent release</b>
Common practices vary across sites thus conservative process release estimates used.

- **Input** environmental Exposure Assessment, standard parameters defined by spERCs:
  - Tonnage used, emission days, dilution factors
  - Release fractions to air, water and soil during process
  - Applied Removal Efficiency (air), can be found in ES output

# Example Section 2 - 2.2 Control of environmental exposure

## Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: 0 %  
No secondary wastewater treatment required.

Risk from environmental exposure is driven by freshwater.

Treat air emissions to provide a typical removal (or abatement) efficiency of: 70 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of = 0 %

## Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Prevent discharge of undissolved substance to or recover from wastewater.

Sludge should be incinerated, contained or reclaimed.

## Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m<sup>3</sup>/day

Estimated substance removal from wastewater via domestic sewage treatment is: 94.6 %

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1800000 kg / day

Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 94.6 %

## Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

## Conditions and measures related to external recovery of waste

External recovery and recycling of waste should comply with applicable local and/or national regulations [ERW1]

- **Output environmental Exposure Assessment:**
  - Risk Driving compartment
  - Required RMMs: Waste Water Treatment Plant
  - Applied Air Removal Efficiency



# ESs environment: DU compliance

- **Parameters to check to ensure REACH compliance:**
  - RMMs required?
    - Requirement driven by [Risk Driving Compartment](#) (water or air related)
    - Parameters to check:
      - [Waste Water Treatment requirement \(on site or third party\)](#)
      - [Air Removal technology assumption/requirement](#)
  - Amount of product to be used safely?
    - [Msafe](#): maximum daily tonnage of the product guaranteeing safe use for a specific application
- GES “standard” exposure assessments require relatively simple check to show REACH compliance

# ESs environment: DU compliance (2)

- Possible outcomes from local REACH environmental assessment:
  - No Risk Management Measures (RMMs) are required to ensure safe use
  - Default RMMs assumed in assessment provide safe use
  - Default RMMs assumed in assessment do not provide safe use

**Outcomes reflect a “hypothetical site” with conservative (spERC) operating conditions**

- **Site tonnage, Days of operation, Wastewater flow, Receiving water dilution**
- Downstream users will have to check to ensure their RMMs / OCs are equivalent to the ones presented in the local REACH assessment
- In some cases, scaling using site-specific values will be required to determine if RMMs / OCs for an actual site meet the RMMs / OCs in the REACH exposure assessments
  - **Data provided on ext-SDSs should provide the key inputs for applying scaling**

# GES (scaling) tool

Fraction in Mixture (weight/weight)	1	<b>D/S User Scale</b>	
M <sub>SPERC</sub> (kg/d)	18.08	730	M <sub>SITE</sub> (kg/d)
Receiving Water Dilution (Fresh or Marine)	10	10	
Emission days per year	20	365	
Wastewater treatment plant flow (m <sup>3</sup> /d)	2000	24000	
Risk Driving Compartment (Code)	10		M <sub>SAFE</sub> calculation
Release Fraction to Air (prior to RMM)	0.15		
Release Fracton to Wastewater (prior to RMM)	0		
Onsite Removal Efficiency - Air (%)	80		Required Removal Eff. - Air (%)
Required Removal Efficiency - Wastewater (%)	0		
Onsite Removal Efficiency - Wastewater (%)	0		
Offsite Removal Efficiency - Wastewater (%)	96		
Total Removal Efficiency - Wastewater (%)	96		
M <sub>SAFE</sub> (kg/d)	4100000		
Risk Driving RCR - Air compartment driven	3.80E-05		
Risk Driving RCR - Water compartment driven	3.40E-05		

## Risk-driving Compartment Number Code:

1 - Wastewater Treatment Plant Microbes; 2 - Freshwater; 3 - Freshwater Sediment; 4 - Freshwater Secondary Poisoning;  
 5 - Marine Water; 6 - Marine Sediment; 7 - Marine Secondary Poisoning; 8 - Soil; 9 - Terrestrial Secondary Poisoning;  
 10 - Humans via Indirect Exposure (primarily inhalation); 11 - Humans via Indirect Exposure (primarily ingestion)

Thanks!  
Questions?



# Example Section 2 - 2.2 Control of environmental exposure

<b>Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil</b>
If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: 0 % No secondary wastewater treatment required. Risk from environmental exposure is driven by freshwater. Treat air emissions to provide a typical removal (or abatement) efficiency of: 70 % Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of = 0 %
<b>Organisation measures to prevent/limit release from site</b>
Do not apply industrial sludge to natural soils. Prevent discharge of <u>undissolved</u> substance to or recover from wastewater. Sludge should be incinerated, contained or reclaimed.
<b>Conditions and measures related to municipal sewage treatment plant</b>
Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m <sup>3</sup> /day Estimated substance removal from wastewater via domestic sewage treatment is: 94.6 % The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1800000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 94.6 %
<b>Conditions and measures related to external treatment of waste for disposal</b>
External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]
<b>Conditions and measures related to external recovery of waste</b>
External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

# Example Section 2 - 2.2 Control of environmental exposure

<b>Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil</b>
If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: 0 % No secondary wastewater treatment required. Risk from environmental exposure is driven by freshwater. Treat air emissions to provide a typical removal (or abatement) efficiency of: 70 % Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of = 0 %
<b>Organisation measures to prevent/limit release from site</b>
Do not apply industrial sludge to natural soils. Prevent discharge of <u>undissolved</u> substance to or recover from wastewater. Sludge should be incinerated, contained or reclaimed.
<b>Conditions and measures related to municipal sewage treatment plant</b>
Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m <sup>3</sup> /day Estimated substance removal from wastewater via domestic sewage treatment is: 94.6 % The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1800000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) <u>RMMs</u> is: 94.6 %
<b>Conditions and measures related to external treatment of waste for disposal</b>
External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]
<b>Conditions and measures related to external recovery of waste</b>
External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

# Example Section 2 - 2.2 Control of environmental exposure

<b>Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil</b>
If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: 0 % No secondary wastewater treatment required. Risk from environmental exposure is driven by freshwater. Treat air emissions to provide a typical removal (or abatement) efficiency of: 70 % Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of = 0 %
<b>Organisation measures to prevent/limit release from site</b>
Do not apply industrial sludge to natural soils. Prevent discharge of <u>undissolved</u> substance to or recover from wastewater. Sludge should be incinerated, contained or reclaimed.
<b>Conditions and measures related to municipal sewage treatment plant</b>
Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m <sup>3</sup> /day Estimated substance removal from wastewater via domestic sewage treatment is: 94.6 % The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1800000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) <u>RMMs</u> is: 94.6 %
<b>Conditions and measures related to external treatment of waste for disposal</b>
External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]
<b>Conditions and measures related to external recovery of waste</b>
External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

# Example Section 2 - 2.2 Control of environmental exposure

<b>Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil</b>
If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: 0 % No secondary wastewater treatment required. Risk from environmental exposure is driven by freshwater. Treat air emissions to provide a typical removal (or abatement) efficiency of: 70 % Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of = 0 %
<b>Organisation measures to prevent/limit release from site</b>
Do not apply industrial sludge to natural soils. Prevent discharge of <u>undissolved</u> substance to or recover from wastewater. Sludge should be incinerated, contained or reclaimed.
<b>Conditions and measures related to municipal sewage treatment plant</b>
Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m <sup>3</sup> /day Estimated substance removal from wastewater via domestic sewage treatment is: 94.6 % The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1800000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) <u>RMMs</u> is: 94.6 %
<b>Conditions and measures related to external treatment of waste for disposal</b>
External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]
<b>Conditions and measures related to external recovery of waste</b>
External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]