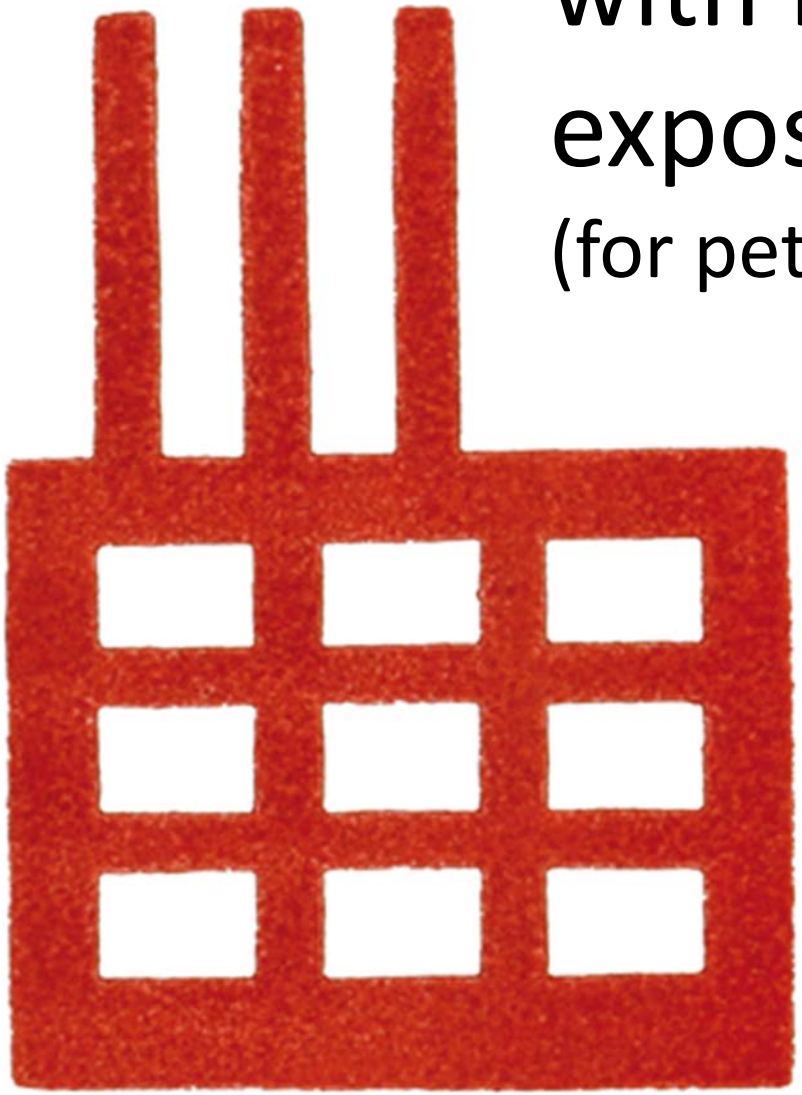
How to check compliance with REACH environmental exposure assessments

(for petroleum products)



Miriam León Paumen

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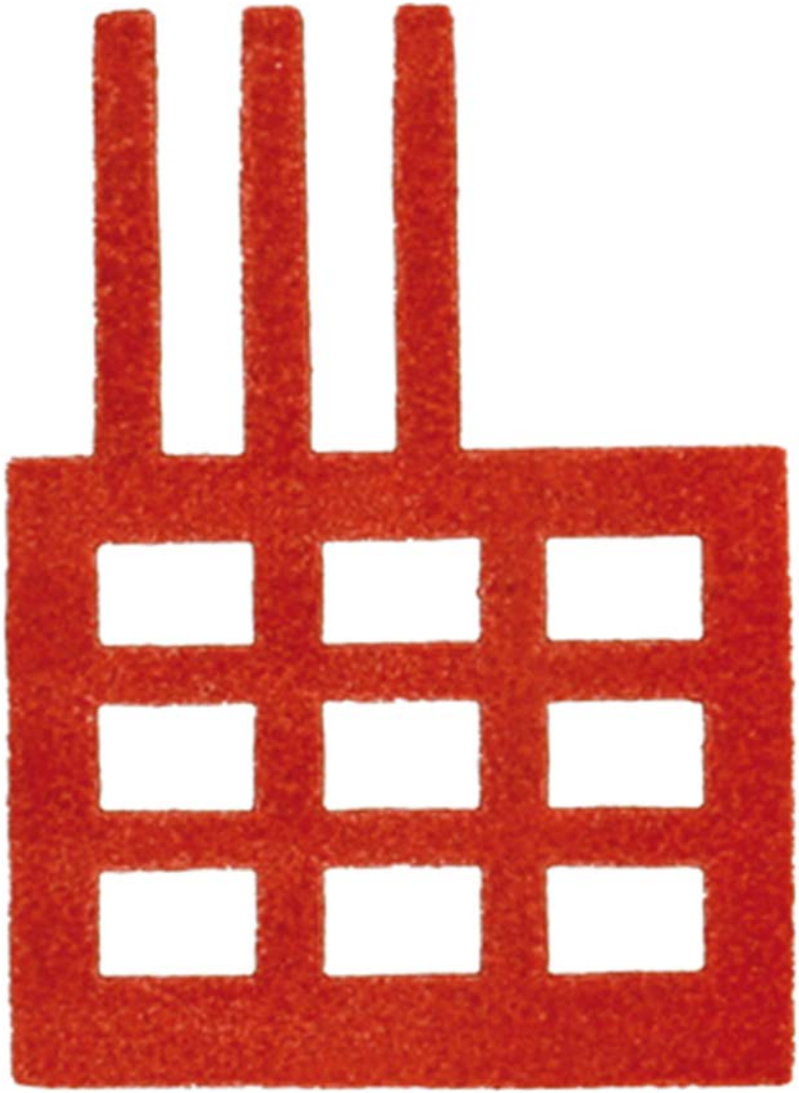
September 25th, 2012

Outline

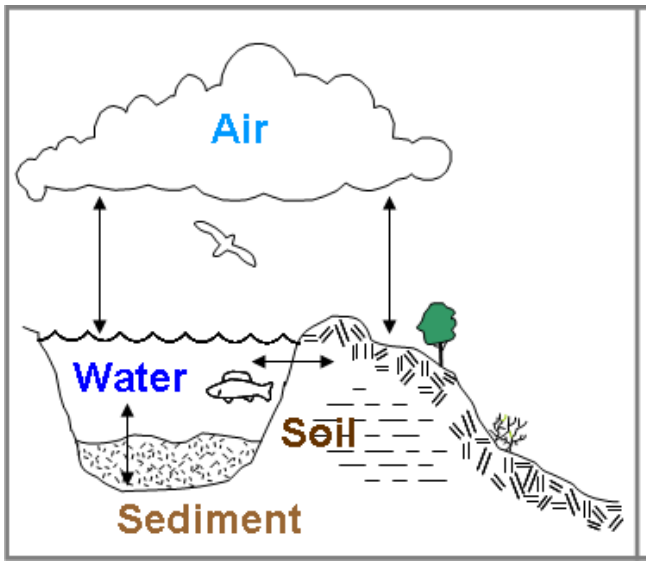


- REACH environmental assessment
  - GES
  - Petroleum substances
  - spERCs
  - PETRORISK
- ext SDSs – environmental
- ES check – environmental
  - GES tool

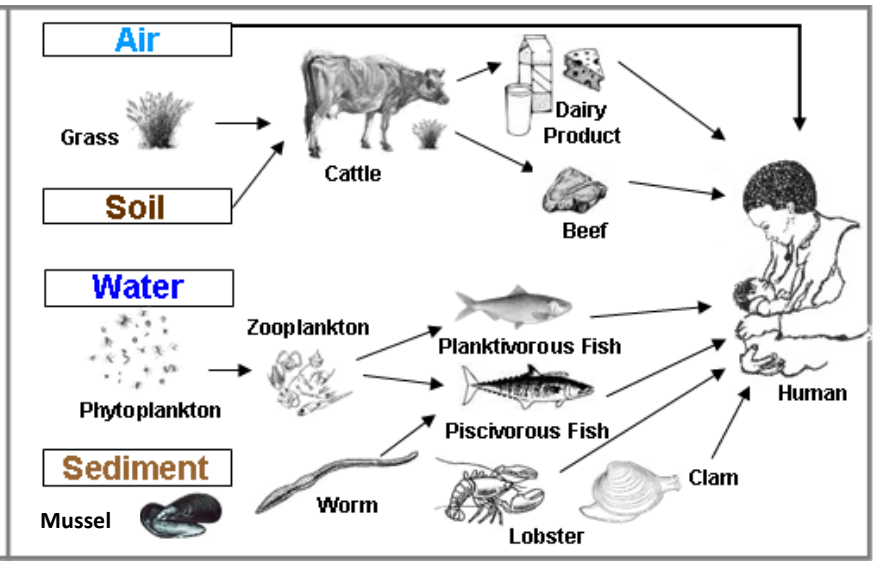
Environmental risk assessments

PRODUCT

Environmental distribution



Exposure pathways



REACH: Exposure Scenarios

RISK

Environmental Exposure Scenarios

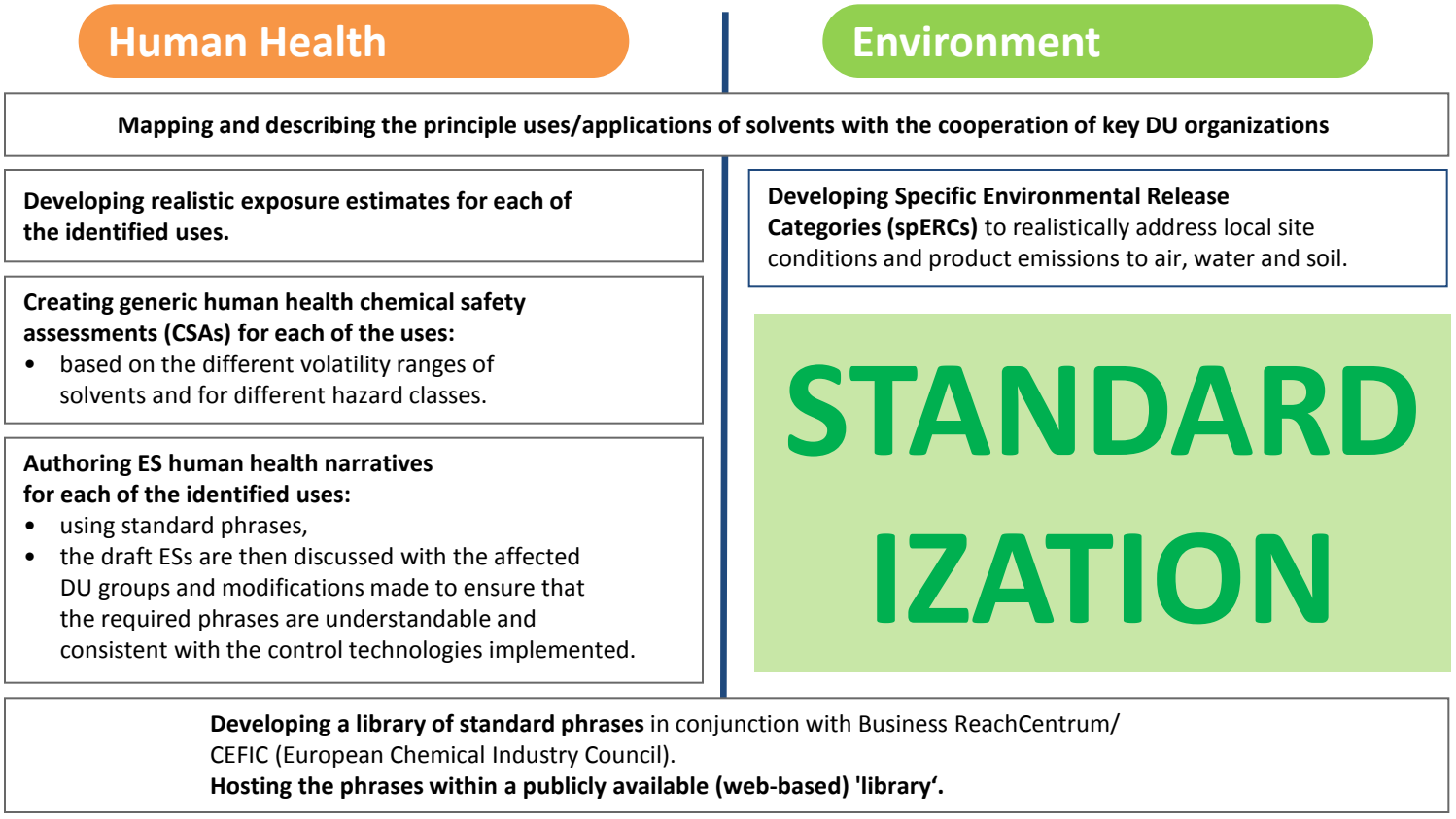
- Environmental ES describes the **assumptions** and **outcome** of a risk assessment for a substance use in a specific sector (e.g. Industrial use of coatings)
  - REACH regulation requires an exposure assessment to be performed for each environmental compartment and exposure route
  - For classified 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 assesment
  - 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)

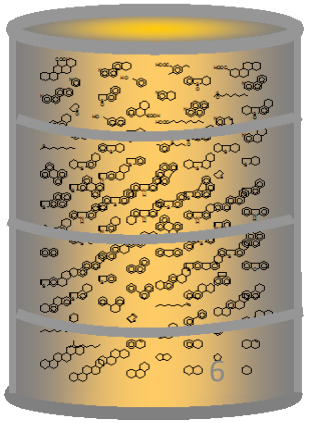
What are GESs?

- 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:

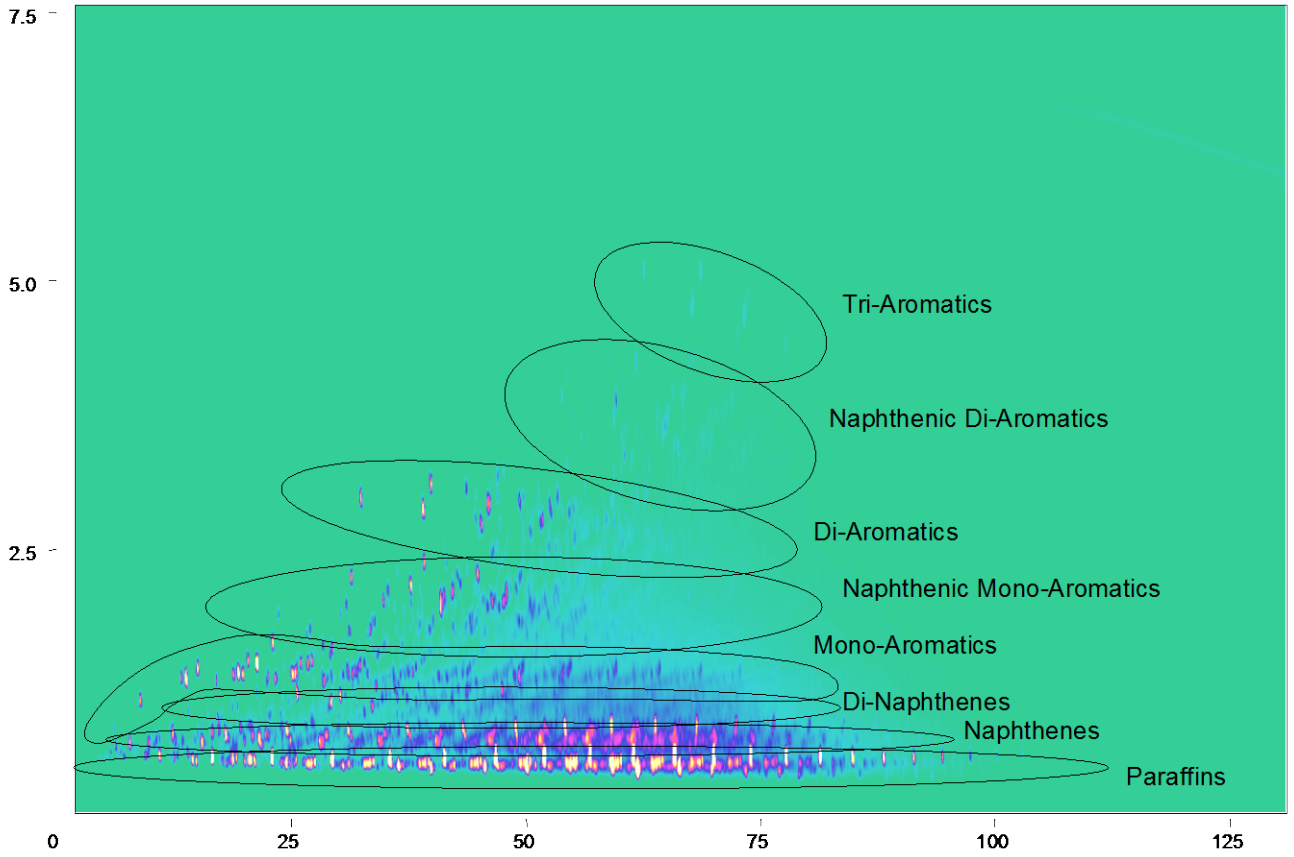


REACH ES example: petroleum substances

- 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

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	Specific ERC (SpERC)
Emission Estimation	Standardized	Standardized
Defaults	Worst case	Good practice
Risk Management Measures	Not included	Considered
Responsibility	ECHA	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 (%)
Identified Solvent								
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

CONCAWE production / use questionnaires

tonnages per use per category

GES allocation

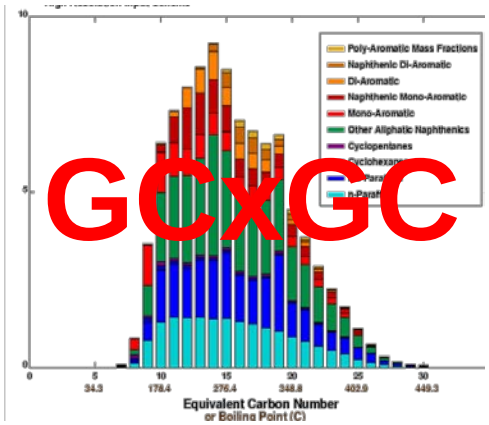
spERCs

emissions to air, water and soil for library structures

Local

Regional

MULTIMEDIA MODEL (PECs)



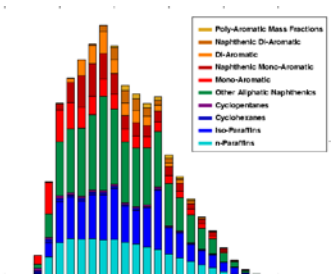
map to CONCAWE library

HC COMPONENTS

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

approach conservative since category emissions applied to substance registrations

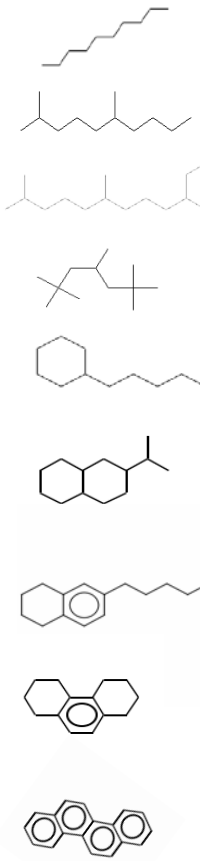
Estimating risk for PSs: PETRORISK



Petroleum Category Composition

Petroleum Category Emissions

Structure



Library

FF/IFs from EUSES Model

Air

Water

Soil

Sediment

Predicted Exposure Concentrations

$PEC_{1, media}$

$PEC_{2, media}$

.....

.....

$PEC_{n, media}$

Safe Use

Yes

$$\text{Risk Ratio} = \sum_{i=1}^{n} (PEC_i / PNEC_i) < 1?$$

No

Toxicity Model

Target Lipid Model

Predicted No Effect Concentrations

$PNEC_{1, media}$

$PNEC_{2, media}$

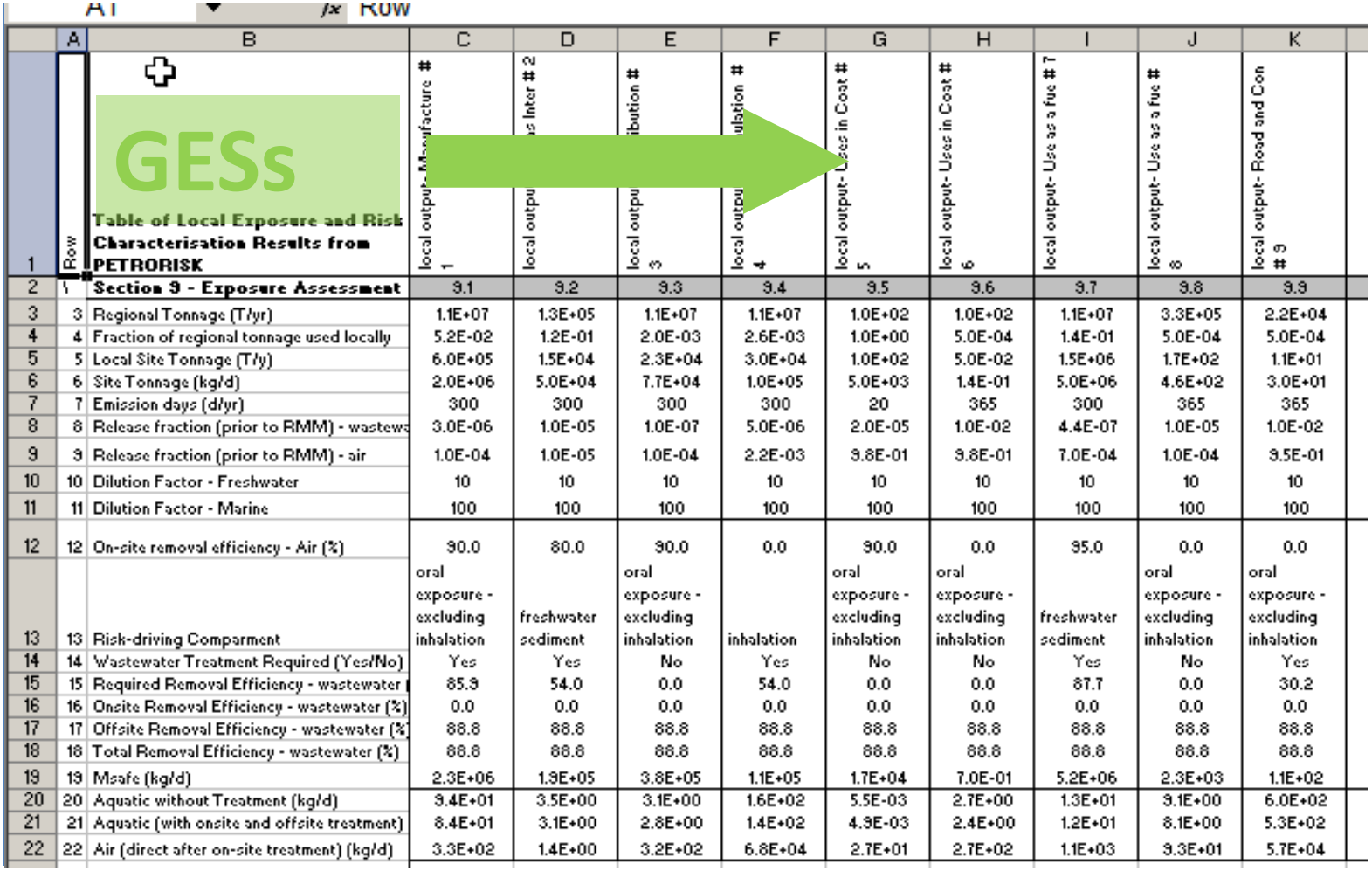
.....

.....

$PNEC_{n, media}$

Refine emissions or risk management measures

PETRORISK local ESs worksheet



GESs

	A	B	C	D	E	F	G	H	I	J	K
1	Row	Table of Local Exposure and Risk Characterisation Results from PETRORISK	local output- Manufacture # 1	local output- Uses Inter # 2	local output- Distribution # 3	local output- Formulation # 4	local output- Uses in Coat # 5	local output- Uses in Coat # 6	local output- Use as a fue # 7	local output- Use as a fue # 8	local output- Road and Con # 9
2	1	**Section 9 - Exposure Assessment**	9.1	9.2	9.3	9.4	9.5	9.6	9.7	9.8	9.9
3	3	Regional Tonnage (T/yr)	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	Fraction of regional tonnage used locally	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	Local Site Tonnage (T/y)	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	Site Tonnage (kg/d)	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	Emission days (d/yr)	300	300	300	300	20	365	300	365	365
8	8	Release fraction (prior to RMM) - wastews	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	Release fraction (prior to RMM) - air	1.0E-04	1.0E-05	1.0E-04	2.2E-03	9.8E-01	9.8E-01	7.0E-04	1.0E-04	9.5E-01
10	10	Dilution Factor - Freshwater	10	10	10	10	10	10	10	10	10
11	11	Dilution Factor - Marine	100	100	100	100	100	100	100	100	100
12	12	On-site removal efficiency - Air (%)	90.0	80.0	90.0	0.0	90.0	0.0	95.0	0.0	0.0
13	13	Risk-driving Comparment	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	Wastewater Treatment Required (Yes/No)	Yes	Yes	No	Yes	No	No	Yes	No	Yes
15	15	Required Removal Efficiency - wastewater	85.9	54.0	0.0	54.0	0.0	0.0	87.7	0.0	30.2
16	16	Onsite Removal Efficiency - wastewater (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
17	17	Offsite Removal Efficiency - wastewater (%	88.8	88.8	88.8	88.8	88.8	88.8	88.8	88.8	88.8
18	18	Total Removal Efficiency - wastewater (%)	88.8	88.8	88.8	88.8	88.8	88.8	88.8	88.8	88.8
19	19	Msafe (kg/d)	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	Aquatic without Treatment (kg/d)	9.4E+01	3.5E+00	3.1E+00	1.6E+02	5.5E-03	2.7E+00	1.3E+01	9.1E+00	6.0E+02
21	21	Aquatic (with onsite and offsite treatment)	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	Air (direct after on-site treatment) (kg/d)	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

Section 2.2 Control of environmental exposure
Product characteristics
Predominantly hydrophobic. Substance is complex UVCB.
Duration, frequency and amount
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
Environmental factors not influenced by risk management
Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100
Other given operational conditions affecting environmental exposure
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
Technical conditions and measures at process level (source) to prevent release
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 m3/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 an 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

- 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**

ESs environment: DU compliance (2)

- **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

GES (scaling) tool

- Used for address customer questions for Fluids BU
  - Scaling for customer sites
- Used (in batch mode) to check internal EM compliance with REACH ESs at production sites

		D/S User Scale	
Fraction in Mixture (weight/weight)	1		
M_{SPERC} (kg/d)	18.08	730	**M_{SITE} (kg/d)**
Receiving Water Dilution (Fresh or Marine)	10	10	
Emission days per year	20	365	
Wastewater treatment plant flow (m^3/d)	2000	24000	
Risk Driving Compartment (Code)	10		**M_{SAFE} 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_{SAFE} (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)

Questions?

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