A method for estimating direct human exposure toxicity potential impacts in product declarations complementary to PEF impact assessment methods

– ProScale –

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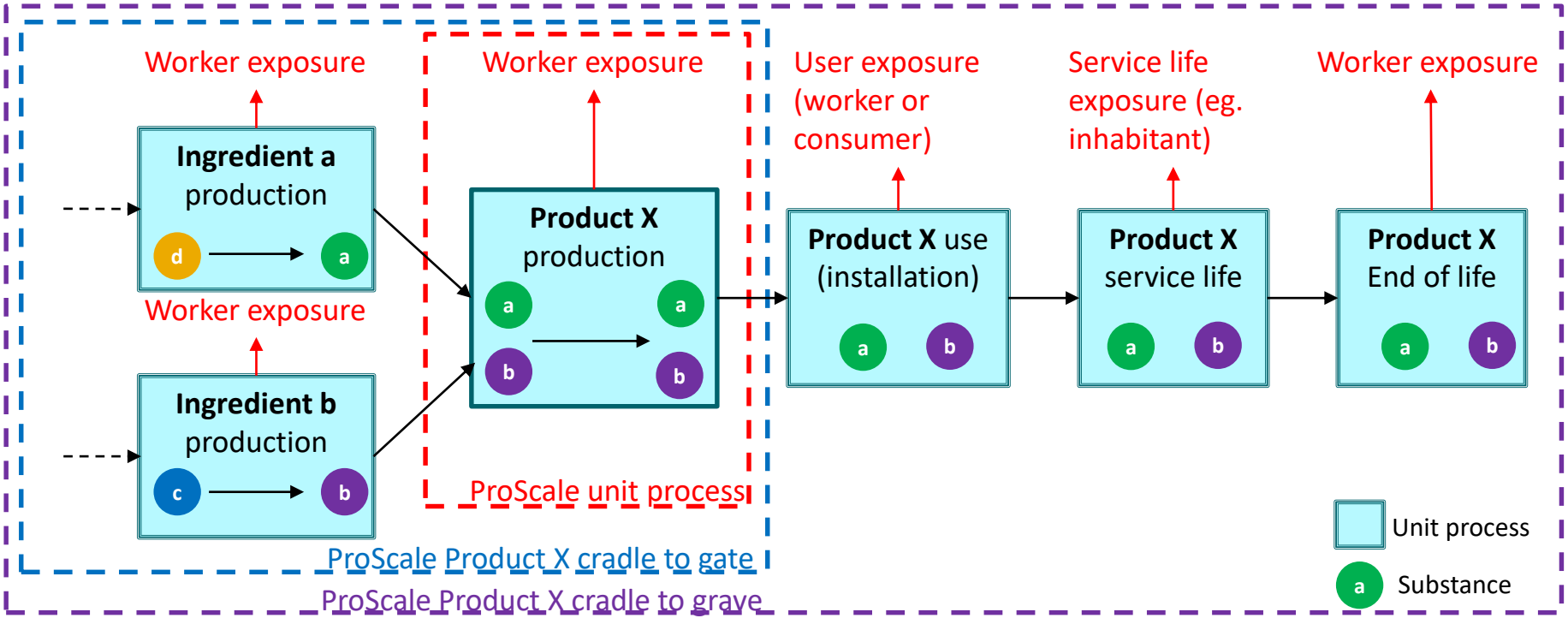
Background

- Need for a method to include direct human exposure in a PEF/EPD context
  - Allow comparison in relation to technical performance
  - Assess the relevant direct exposure potential along the whole life cycle
  - Be relevant for business-to-business and business-to-customer communication.
- Complementary to other approaches
  - As a minimum suitable for ”Additional information”,
  - As ”LCA compatible” as possible
- Use existing data
  - e.g. REACH based

Conceptual life cycle & ProScale



Elements of ProScale – schematic presentation

$$\text{ProScale} = \sum_{\substack{\textit{substances} \\ \textit{unit processes}}} \text{HF} \times \text{ECF} \times \text{PHF} \times \text{MF}$$

HF
Hazard Factor
Substance hazard, based on H-phrase and OEL

ECF
Exposure Concentration Factor
Modelled exposure, based on standard process conditions

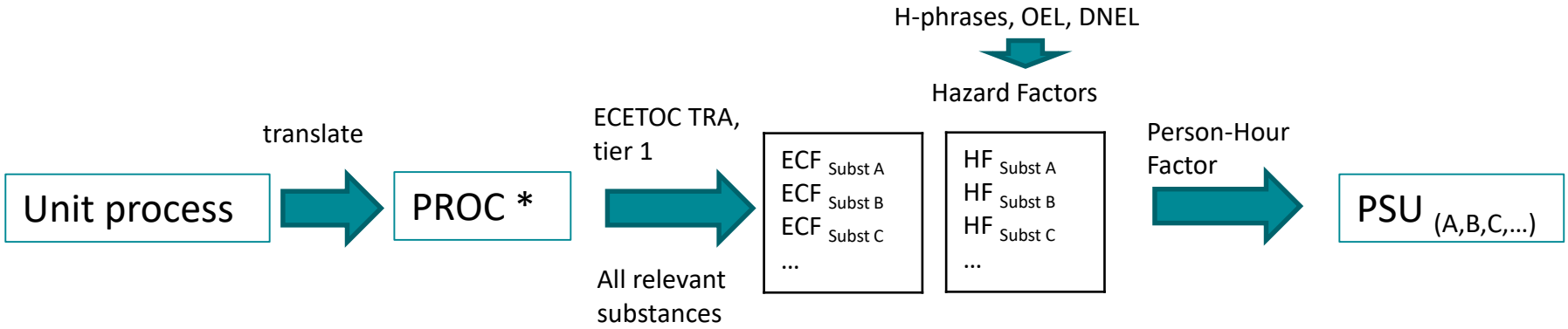
PHF
Person-Hours Factor
Number of person-hours of exposure per mass unit of produced product

MF
Mass Flow
The amount of substance used per functional unit

- Substance specific
- Process specific
- Product system dependent

PSU - ProScale Score for Unit Process

- Logic flow example : industrial process - schematic:
- Exposure Concentration Factor (ECF) based on ECETOC TRA tier 1
- Hazard factors for each substances based on H-phrase and OEL or DNEL
- Combined with Person-Hour Factor (PHF) to achieve a ProScale score
- Conceptually relating dose for exposed group of humans to functional unit



*) Process category (PROC): ECHA guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description
For use and service life processes, different notations than PROC is used

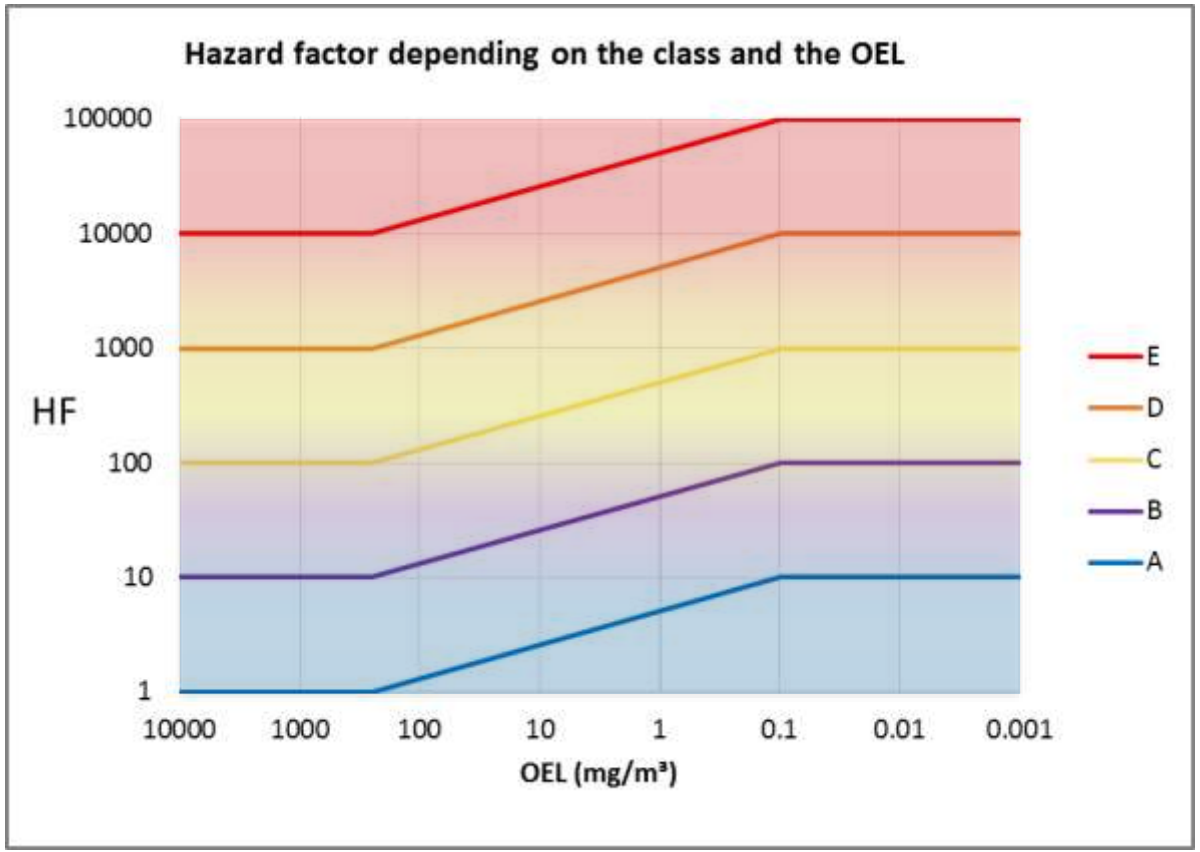
Hazard Factor

H-phrases classification

- H-phrases have been grouped in five ProScale hazard classes
- The H-phrase class of a substance is established separately for each exposure route
- The H-phrase that corresponds to the highest class is determining the class for a substance
- EUH specific H-phrase have been added (for EU only)

ProScale Hazard class	H-phrases according to GHS/CLP, grouped by exposure route
E **10 000 - 100 000** (highest hazard)	All routes : H340, H350, H360, H362
D **1000 - 10 000**	Dermal : H310 Inhalation : H330, H334, EUH032 Oral : H300, All routes : H341, H351, H361, H372
C **100 - 1000**	Dermal : H311, H314, H317, H318, EUH070 Inhalation : H331, EUH029, EUH031, EUH071 Oral : H301, H304 All routes : H370, H373
B **10 - 100**	Dermal : H312, H315, H319, Inhalation : H332, H335 Oral : H302 All routes : H371
A **1 - 10** (lowest hazard)	Dermal : H313, H316, H320, EUH066 Inhalation : H333, H336 Oral : H303, H305,

Hazard factor (HF) numerical transformation



- Unknown OEL => the ProScale Hazard Factor = =maximum of the class
- No H-phrase , but identified OEL or DNEL => Hazard class A
- No H-phrase and No OEL/DNEL => Hazard Factor “0”.

Exposure Concentration Factor

Exposure – input parameters

Basis: ECETOC TRA Tier 1

Inhalation exposure

Parameters:

1. **PROCs** : standardized process categories defined in REACH
2. **Use** : industrial / professional / consumer
3. **Physical state :** solid / volatile
4. **Risk Management Measure (RMM)**: yes / no.
5. **Fugacity** (likelihood to become airborne) :
   negligible / low / medium / high
   requires : **vapor pressure** for volatiles and **dustiness** for solids

Dermal exposure

derived from PROCs and Use (parameters 1 and 2 above)

worst case risk management measures (significant dermal exposure unlikely).

PROC examples

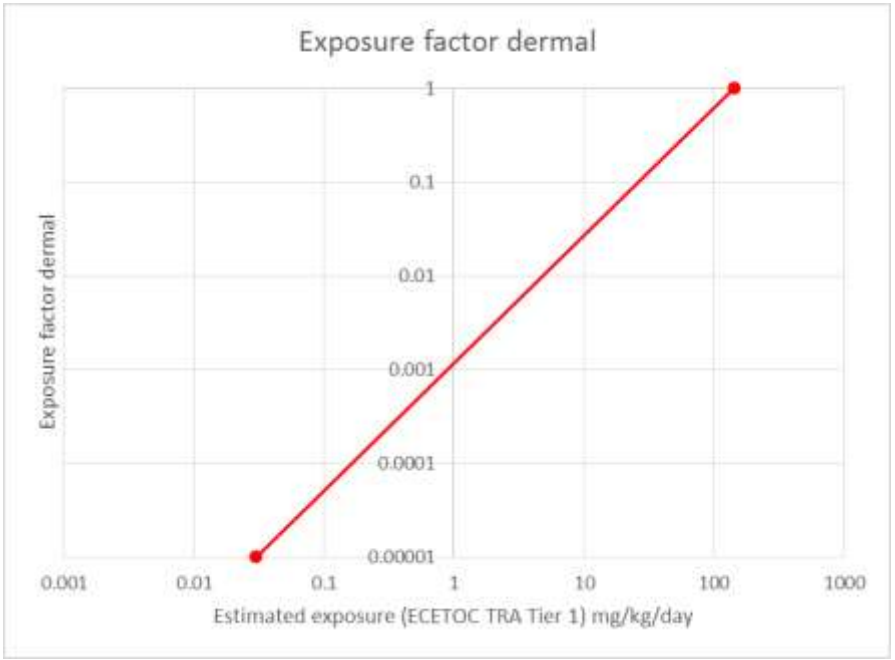
Code	Name
PROC1	Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.
…	
PROC4	Chemical production where opportunity for exposure arises
PROC5	Mixing or blending in batch processes
…	
PROC8b	Transfer of substance or mixture (charging and discharging) at dedicated facilities
…	
PROC14	Tableting, compression, extrusion, palletization, granulation
…	
PROC27b	Production of metal powders (wet processes)
PROC28	Manual maintenance (cleaning and repair) of machinery

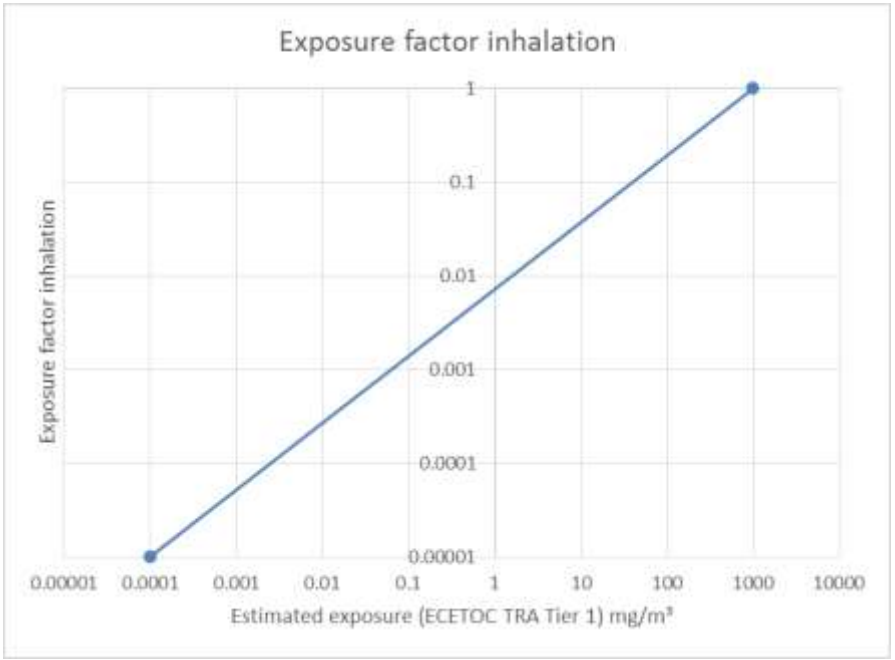
Exposure – example of significance of PROC selection and fugacity level

Initial exposure value (mg/m^3), (no RMM)

		Fugacity level, fluids			
		negligible	low	medium	high
Vapour press. ranges		< 0.00001	>=0.00001- <0.5	0.5 to 10	>10
Example substances			DEHP: 0.001	Styrene: 0.67	Hexane: 17
PROC	1	0.01	0.01	0.01	0.01
	4	0.1	5	20	100
	5	0.1	5	50	250
	8b	0.1	5	25	150

Transformation of modelled exposure into ProScale exposure concentration factor (ECF)





Person-Hour Factor

Person-Hour Factor

- a Person-Hour Factor (PHF) has been introduced
  - transforming the exposure concentration to a dose
  - ProScale score can be related to the functional unit.
- PHF example formulae

$$Person - Hour\ Factor(industrial\ processes)[hr/kg] = \frac{Annual\ hours\ worked\ \left[\frac{hr}{year}\right]}{Annual\ production\ volume\ \left[\frac{kg}{year}\right]}$$

$$Person - Hour\ Factor(installation)[hr/kg] = \frac{Exposure\ duration\ [hr]}{Amount\ of\ product\ used\ [kg]}$$

$$Person - Hour\ Factor\ (service)[hr/service\ unit] = \frac{Exposure\ duration\ [hr]}{Amount\ of\ service\ [service\ unit]}$$

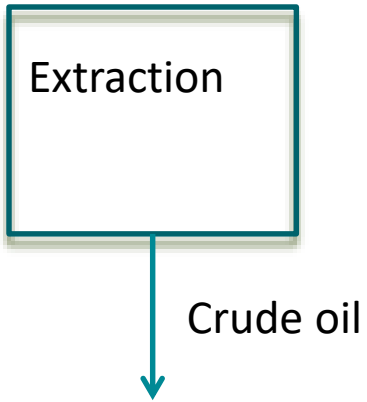
- Default Person-Hour Factors (PHF) have been established based on reference data such as BREF documents (Best available techniques Reference document developed under the IPPC Directive and the IED)

Person-Hour Factor, examples

Type of production process	Hours / produced amount (hr/kg)
Organic commodity chemicals manufacturing, large to medium size chemical plant	**1E-03**
Naphta cracker	1.0E-03
Organic commodity chemicals manufacturing, small to medium size chemical plant	**3E-03**
Lubricant production	2.7E-03
Inorganic chemicals manufacturing, large to medium size chemical plant	**6E-03**
Chlorine manufacturing	6.4E-03
Fine/specialty chemicals manufacturing, small to medium size chemical plant	**1E-01**
Manufacturing of fine organic chemicals such as pigments and dyes, flame retardants, plasticisers such as phtalate esters, pharmaceuticals etc	9.6E-02
Plastics manufacturing	**3E-03**
Polymer manufacturing	2.8E-03
Plastics processing	**1E-02**
Plastics extrusion etc	1.28E-02
Mixing and blending batch processes, such as paint manufacturing	**2E-02**
Liq. Coatings production	1.7E-02
Oil extraction	**4E-04**

Example – Crude oil extraction

Step-by-step

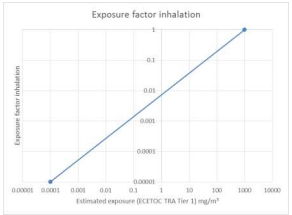


- Assign PROC => PROC 2 (for illustration)
- Substance(s): crude oil
  - Establish HF
    - H-phrase H350 => ProScale class E
    - OEL => not found => ProScale **HF = 100000** (highest in class)
  - Establish ECF
    - Volatile: Vapour pressure 55.25 kPa => ”high”
    - RMMs: No
    - Exposure (inhalation) => 25 mg/m3 => (transformation) => **ECF = 0.07**
  - Establish PHF: **0.0004**
  - Mass flow: 1 kg (to get result for 1 kg)
- **ProScale score = 100000 * 0.07 * 0.0004 * 1 = 2.8** (per kg crude oil)

Service life

Exposure Concentration Factor – Service life

- $Exposure = \frac{m}{Q_{air}} = \frac{SER \times A_{product} \times time}{V_{room} \times \alpha \times time}$
- Q_{air} - standard: **15** m^3/h for a 30 m^3 room with 12 m^2 floor area
- SER = Specific area Emission Rate (kg/m^2 h)
  - measured or modelled
  - Example: SER for DEHP from PVC flooring = **0.4 µg/m²h** (literature)
- Steady-state concentration = 0.4*12/15 =4.8/15 = 0.32 $\mu g/m^3$
- ECF is acheived through numerical transformation = **0.00002**



Person Hours Factor – Service life

- The Person-Hours Factor describes the number of people exposed and the time they are exposed.
- $PHF_{indoor\ exp.} = Population\ density \times time\ indoor = \frac{Population}{Indoor\ floor\ area} \times time\ indoor$

- $Population_{EU} \approx 510 \times 10^6$ (Eurostat, 2016. Population EU28 1st of January 2016)
- $Indoor\ floor\ area\ \approx 25 \times 10^9\ m^2$ (EC, 2016. SWD (2016)24 final)

→ $Population\ density_{EU} \approx 0.02$

- Time fraction indoor =100 % (conservative estimate)

ProScale score for Service life calculation example: flooring

- Standard room 12 m2 => 24 kg PVC flooring
- Lifetime 10 years => 88000 hours
- Population density 0.02 pers/m2 => PHF = 880 h/kg
- ECF (DEHP from PVC flooring) => ECF = 0.00002
- HF for DEHP (H-code: H360) => HF = $4.14*10^4$
- ProScale score: HF*ECF*PHF => 728.64 (per kg flooring)

ProScale “Tiers”

In parallel: Other regions and sectors

Further Refinements:
- Routes aggregation
- ‘Globally ’ agreed OEL/DNEL
- Service-life model
- Etc…

Tier 4: Humans via the environment and ecotoxicity

Exposure of humans via the environment to substances used/contained

Humans via the environment

Ecotoxicity

Exposure of species in the environment to substances used/contained

Tier 1: Current status : direct human toxicity

Raw materials → Production → Application

Exposure of workers to substances used/contained

Tier 2: Cradle-to-Grave

Service-Life → End-of -Life

Exposure of users to substances contained

Exposure of workers to substances contained

Exposure of workers to substances used/contained during energy production/extraction + tank filling

Energy for production and transport

Tier 3: Energy and Transport

Up next

- ProScale Guidance
  - Release Soon

- ProScale conference
  - October 5th

ProScale Conference

Brussels, 5 October 2017

ProScale – a method to assess the toxicological potential of product systems in a life-cycle perspective

A conference organized by the ProScale consortium.
Open to industry stakeholders and experts.

Thursday 5 October 2017, Brussels, Hôtel Métropole, 10.00 to 16.00.

Free participation, number of seats limited.

Pre-registration by email to proscale@uetlibergpartners.com

A detailed agenda will be sent in early September.

Thank you for listening!

And thanks to all the hard working colleagues!

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