# MORNING PROGRAMME

| | | |
|---|---|---|
| 10:00-10:10 | Welcome & introduction | Eric Bischof, Covestro, Chair of the ProScale consortium |
| 10:10-10:25 | Reconciling risk Assessment & Life-cycle Assessment? | Guy Castelan, PlasticsEurope |
| 10:25-10:55 | The ProScale Method – an introduction | Tomas Rydberg, IVL |
| *10:55-11.15* | *Coffee break* | |
| 11:15-11:45 | Case Studies: ProScale results | Peter Saling, BASF<br>Tomas Rydberg, IVL |
| 11:45-12:00 | Added Value of ProScale relative to PEF, EPD, LCA | Quentin de Hults, BASF |
| 12:00-12:30 | Questions & Answers | |
| *12:30-13:30* | *Lunch* | |

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# ProScale Conference

A method for assessing the toxicological potentials of product systems in a life cycle perspective

Brussels, Hôtel Métropole | 5 October 2017 9.30 to 17.00

# THE ProScale™ METHOD – AN INTRODUCTION

TOMAS RYDBERG, IVL

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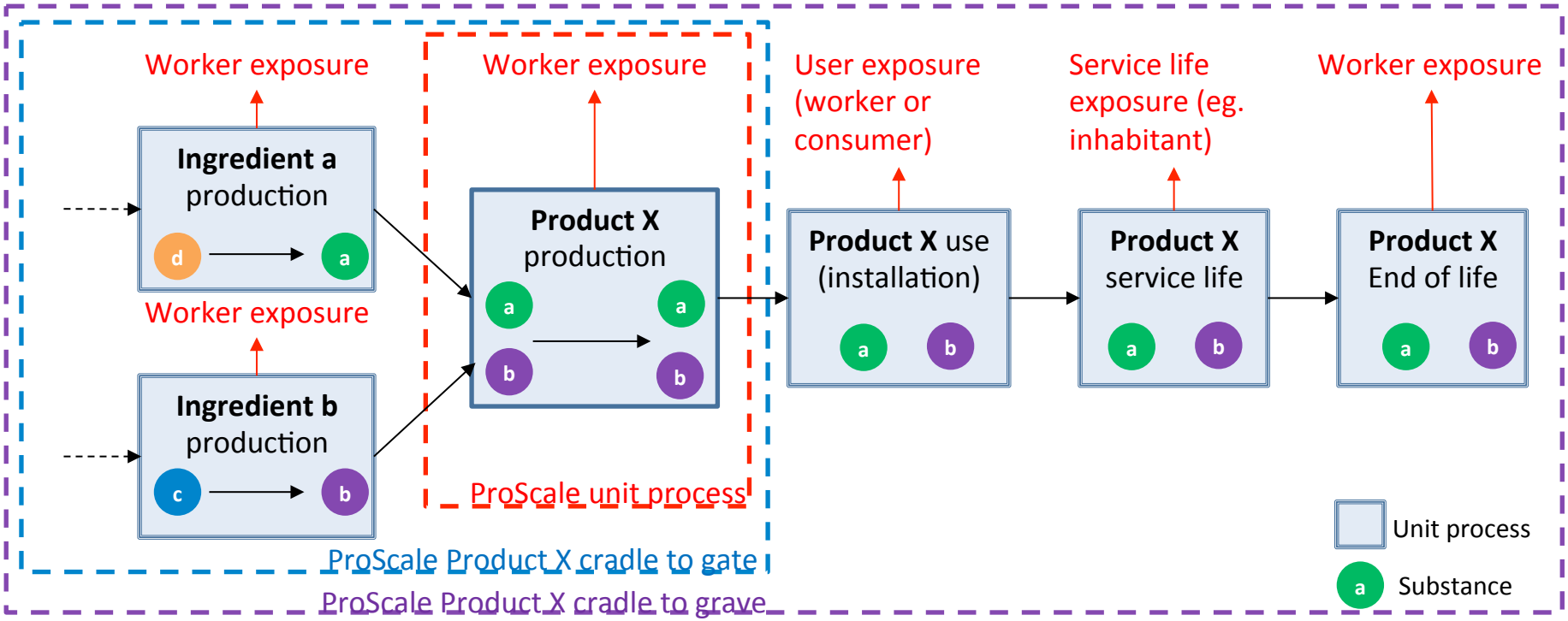
# Background

- 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

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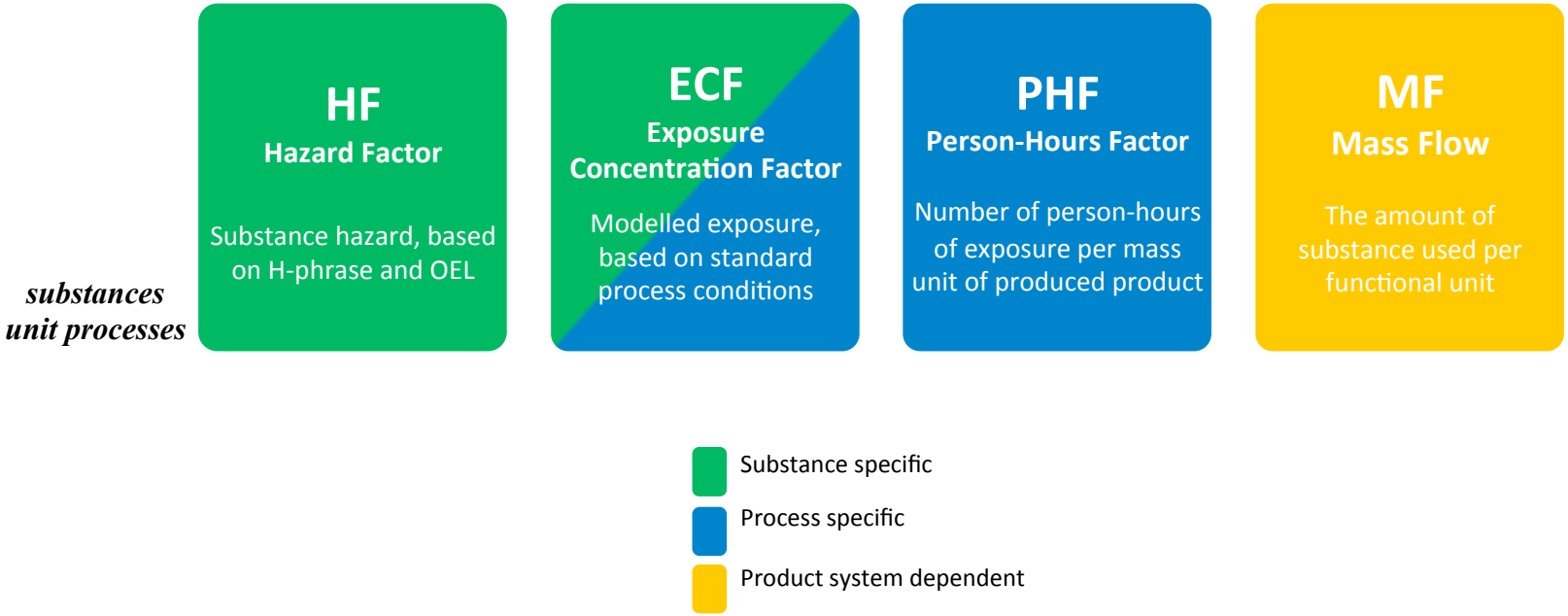
# Elements of ProScale – schematic presentation

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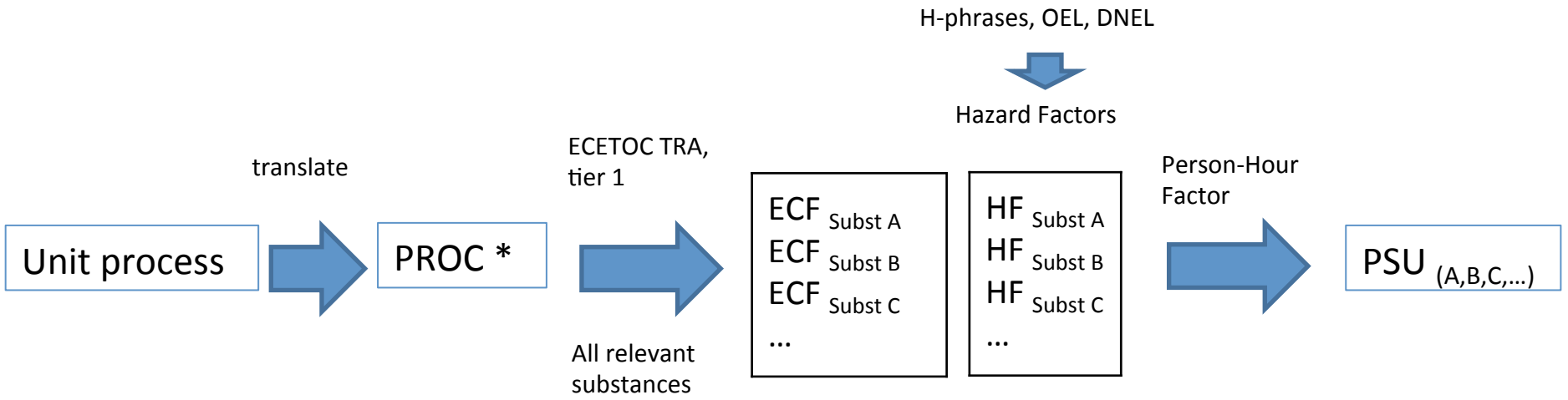
# PSU - ProScale Score for Unit Process

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




*) 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

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# Hazard Factor

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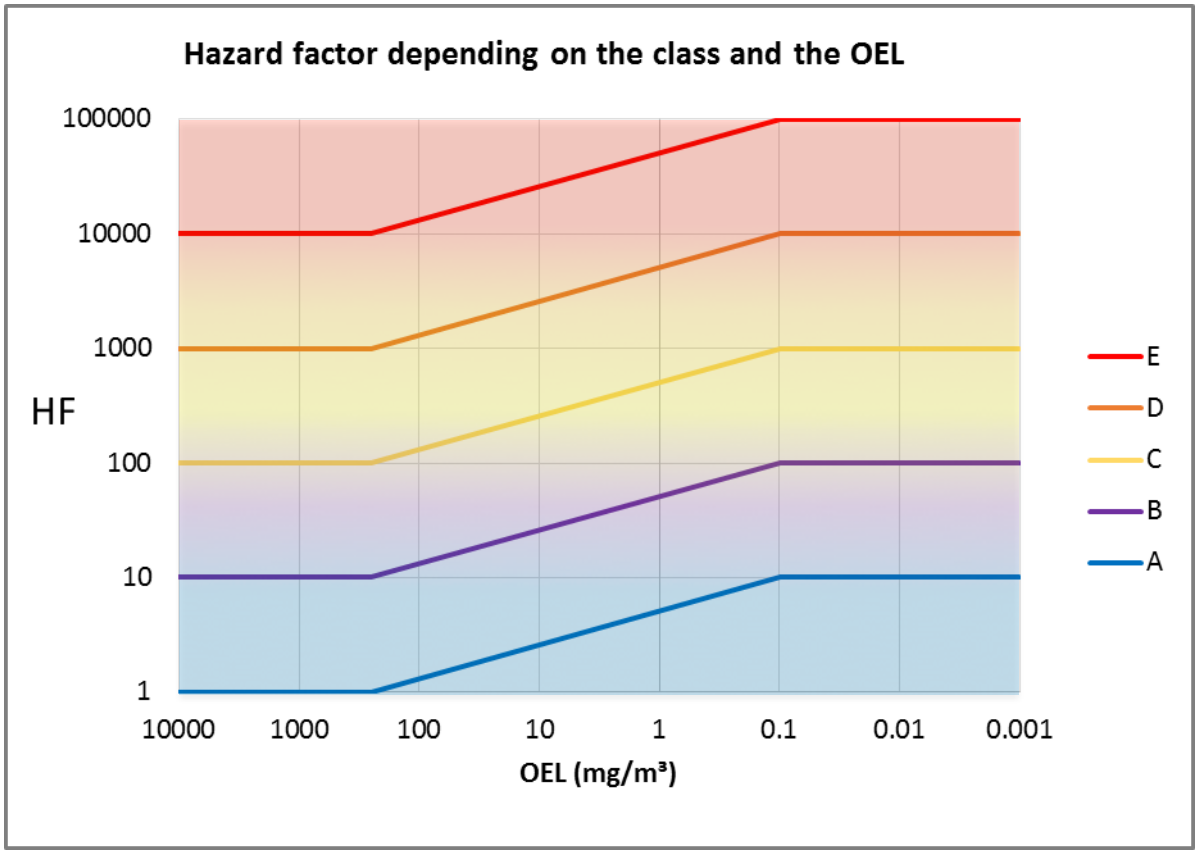
# H-phrases classification

- 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**<br>**10 000 - 100 000**<br>(highest hazard) | All routes : H340, H350, H360, H362 |
| **D**<br>**1000 - 10 000** | Dermal : H310<br>Inhalation : H330, H334, EUH032<br>Oral : H300,<br>All routes : H341, H351, H361, H372 |
| **C**<br>**100 - 1000** | Dermal : H311, H314, H317, H318, EUH070<br>Inhalation : H331, EUH029, EUH031, EUH071<br>Oral : H301, H304<br>All routes : H370, H373 |
| **B**<br>**10 - 100** | Dermal : H312, H315, H319,<br>Inhalation : H332, H335<br>Oral : H302<br>All routes : H371 |
| **A**<br>**1 - 10**<br>(lowest hazard) | Dermal : H313, H316, H320, EUH066<br>Inhalation : H333, H336<br>Oral : H303, H305, |

# Hazard factor (HF) numerical transformation




- Defined data source hierarchies for H-phrases and OEL
- Unknown OEL => the ProScale Hazard Factor = maximum of the class
- CMRs with OEL : HF divided by a factor 3
- No H-phrase , but identified OEL or DNEL => Hazard class A
- No H-phrase and No OEL/ DNEL => Hazard Factor “0”.

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# Exposure Concentration Factor

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# 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).

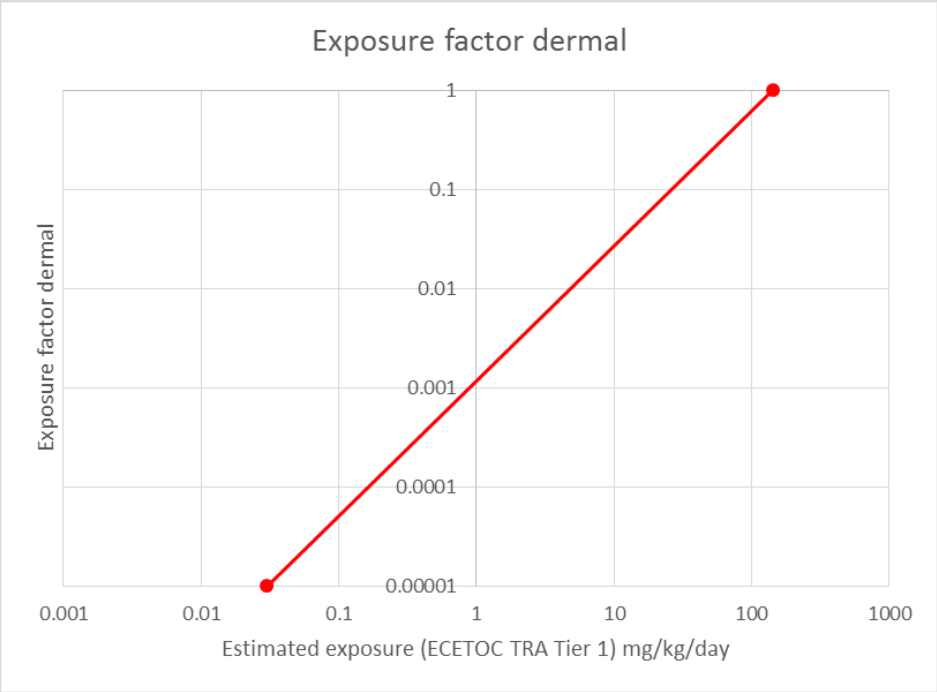
# PROC examples

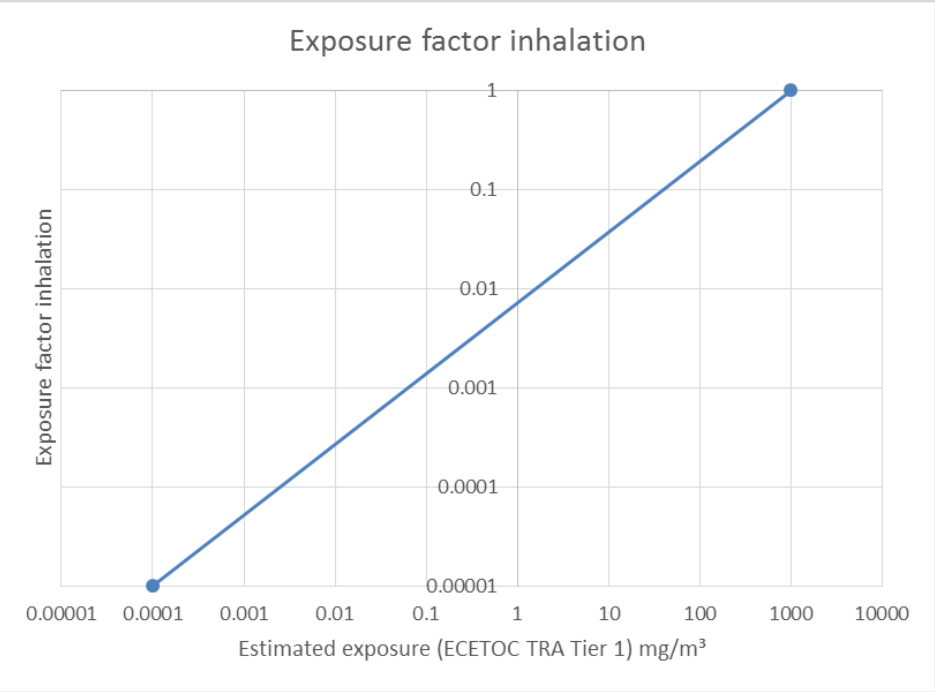
| Code | Name |
|---|---|
| PROC1 | Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions. |
| … | |
| PROC4 | Chemical production where opportunity for exposure arises |
| PROC5 | Mixing or blending in batch processes |
| … | |
| 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

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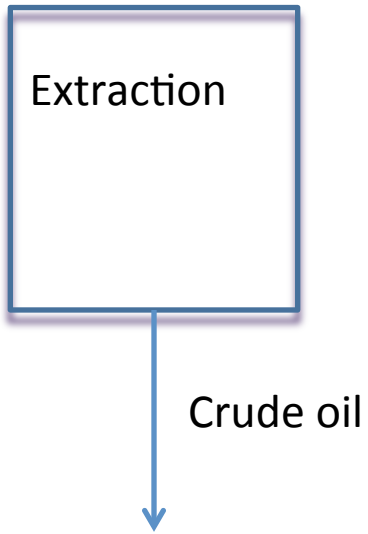
# Step-by-step




- 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)

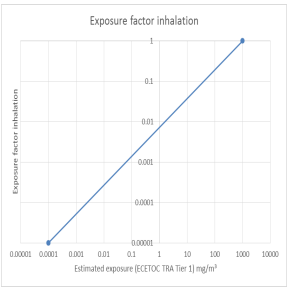
# Service life

# Exposure concentration Factor – Service Life

- The exposure is a function of the substance release rate and the air exchange rate

$$Exposure = \frac{m}{Q_{air}} = \frac{SER \times A_{product} \times time}{V_{room} \times \alpha \times time}$$

- $m$ is the released amount of a substance from the studied subject during a given time
- $Q_{air}$ is the ventilated air volume during a given time, where α is a 0.5 $h^{-1}$ in a standard room
  - *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) can be either measured or modelled
  - Example: SER for DEHP from PVC flooring = 0.4 µg/$m^2$h (literature)
- Steady-state concentration= 0.4*12/15 = 4.8/15 = 0.32 µg/$m^3$
- ECF is achieved through numerical transformation **= 0.00002**

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# 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 $m^2$ => 24 kg PVC flooring
- Lifetime 10 years => 88000 hours
- Population density 0.02 pers/$m^2$ => PHF = 880 h/kg
- ECF (DEHP from PVC flooring) => ECF = 0.00002
- HF for DEHP (H-code: H360, has OEL) => HF = $1.38*10^4$

- ProScale score: HF*ECF*PHF => 243 (per kg flooring)

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Tomas Rydberg, tomas.rydberg@ivl.se

# THANK YOU FOR YOUR ATTENTION

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