The method

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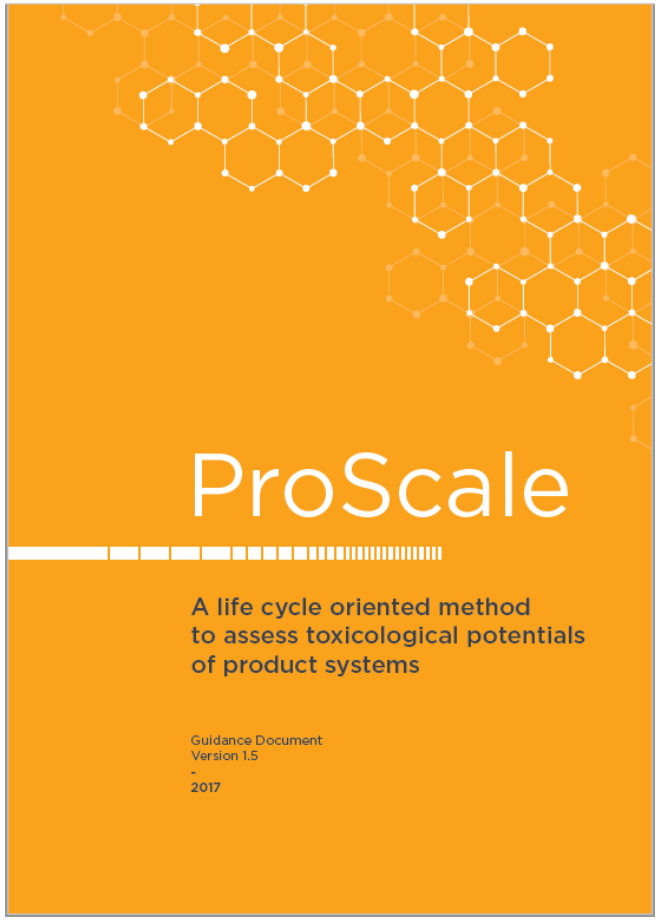
ProScale

Method details in ProScale Guidance doc



https://proscale.org/english/ivl/publications/publications/proscale---a-life-cycle-oriented-method-to-assess-toxicological-potentials-of-product-systems-2017.html

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 worked per mass unit of produced product

MF
Mass Flow
The amount of substance used per functional unit

Default Settings:	H-phrases + OEL/DNEL	ECETOC TRA V3.1	BREF	”Bill-of-material”

Substance specific
Process specific
Product system dependent

HF

Hazard Factor

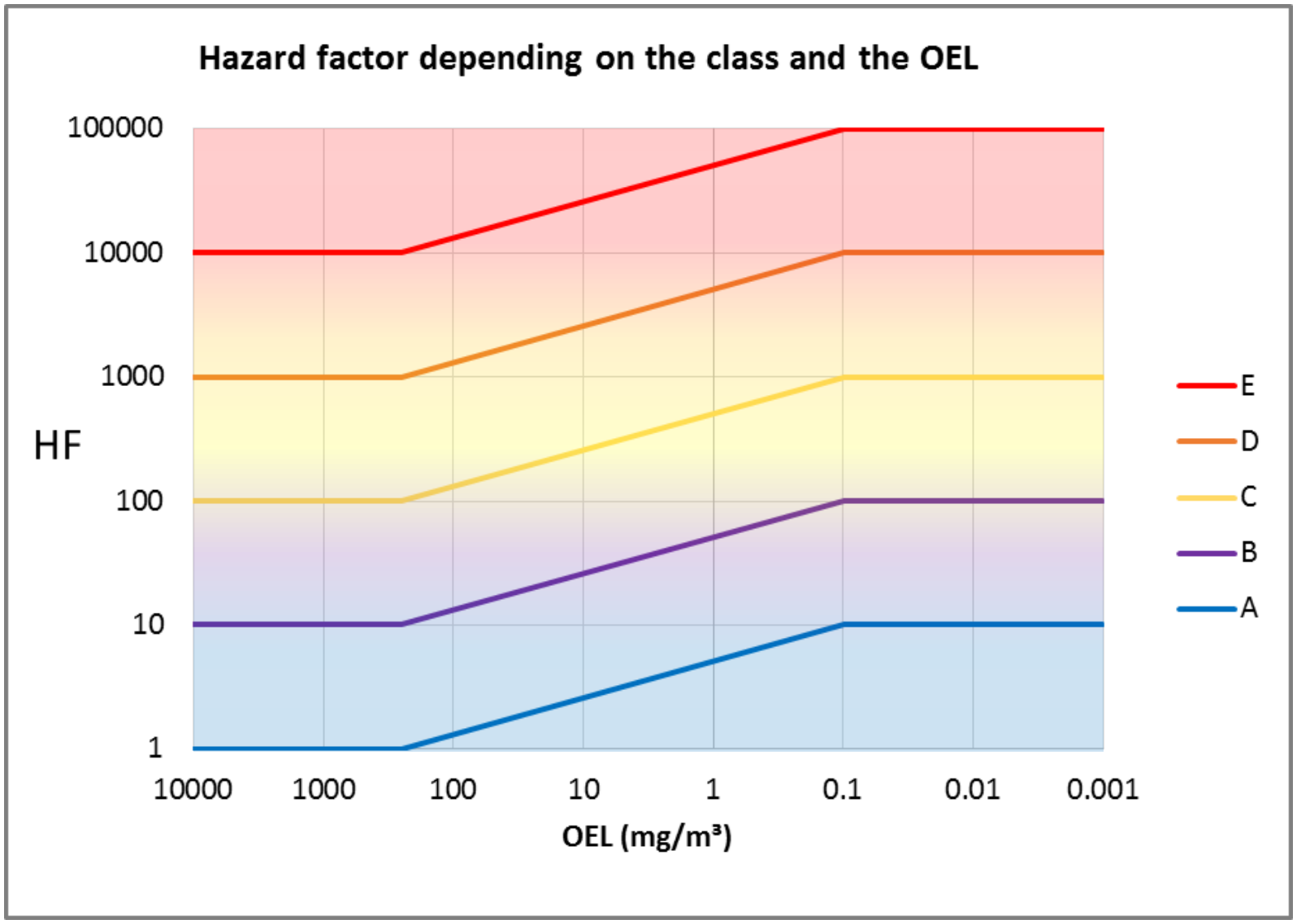
Substance hazard, based on H-phrase and OEL

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



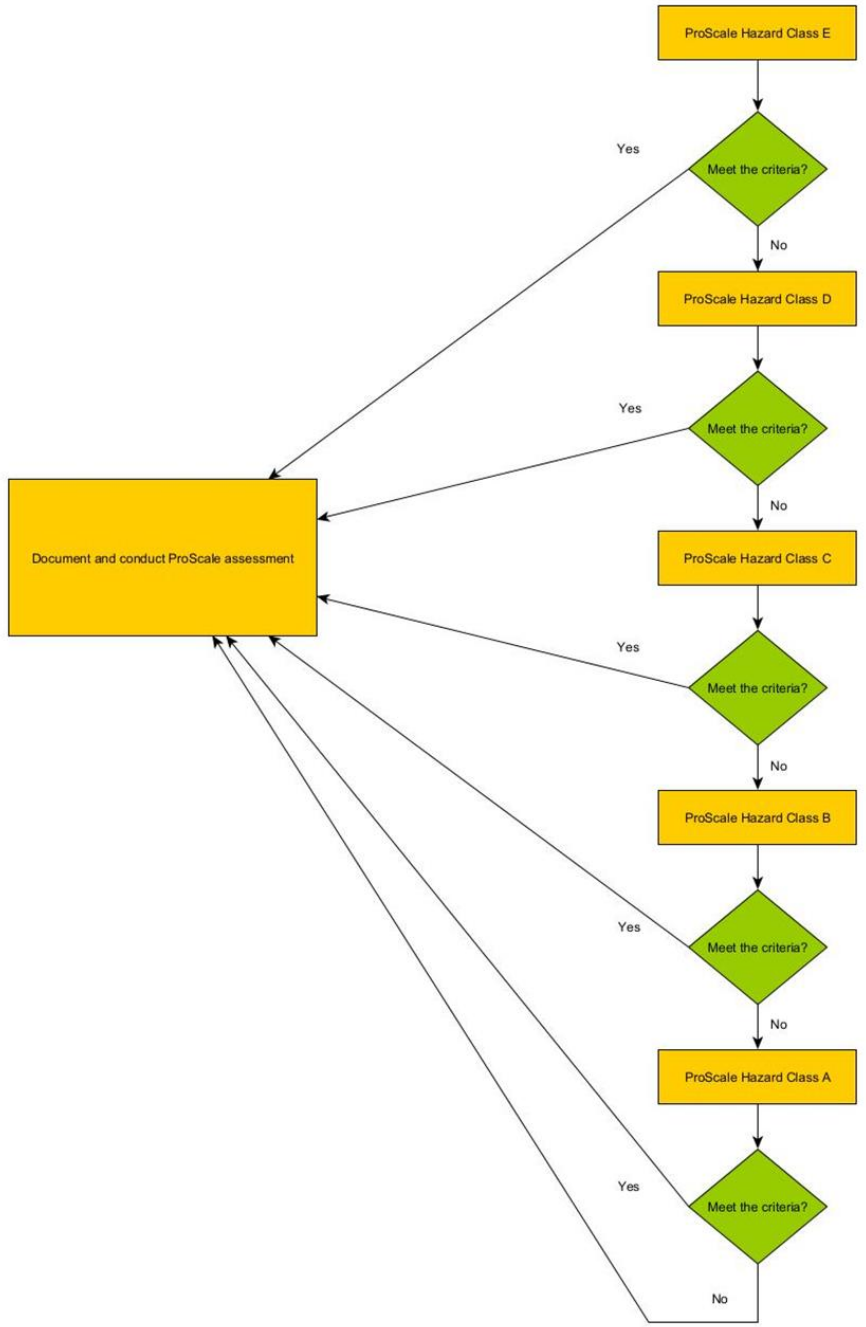
- Unknown OEL => the ProScale Hazard Factor = =maximum of the class
- No H-phrase , but identified OEL or DNEL => Hazard class A
- Assessed with no H-phrase and No OEL/DNEL => Hazard Factor “0”.

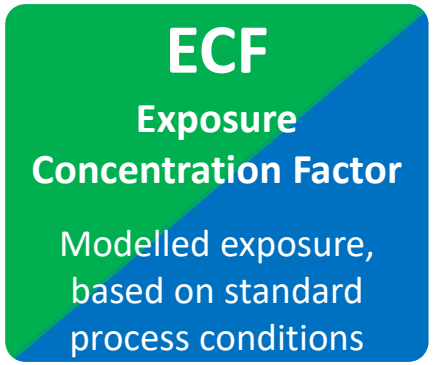
What if a substance has no classification (yet) and no OEL/DNEL

- Option 1: assume highest possible score = =100 000

- Option 2: Run consecutive computational models for the hierarchy/order

Class E => Class D => Class C => Class B => Class A




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

ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on Information Requirements and Chemical Safety Assessment

Chapter R.12: Use description

Version 3.0
December 2015

Process Categories (PROC)

Descriptor list for Process Categories (PROC)

The process categories define tasks, or process types from the occupational perspective. The PROCs are also differentiated by taking into account the exposure potential for workers during the respective tasks or process types. This descriptor can be assigned to workers' activities contributing to a use. The categories are meant to support harmonised and consistent exposure assessment across sectors and supply chains.

The use descriptor included in the description of use is expected to reflect the nature and scope of the activities. The explanations and examples below should be looked at in order to ensure that the process category assigned is appropriate.

When no appropriate descriptor is available "PROC0 - other" should be selected and a description should be provided.

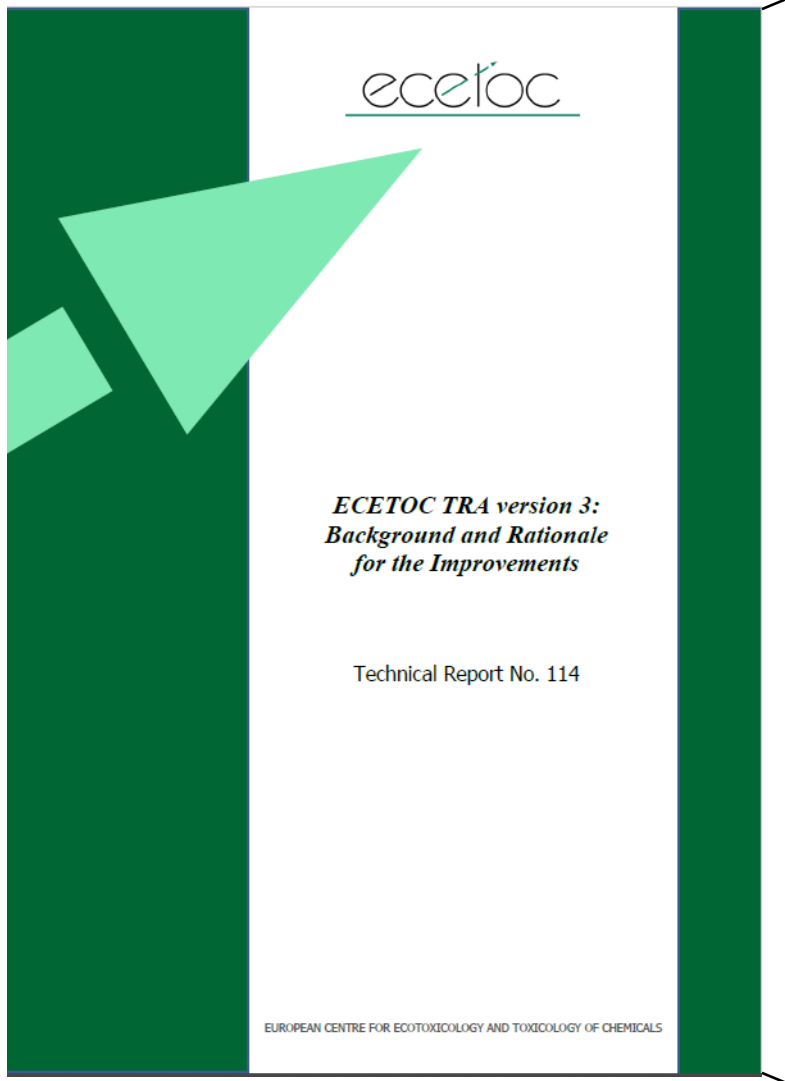
Table R.12- 11: Descriptor list for Process categories (PROC)

Code	Name	Explanations and examples
PROC1	Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.	Describes the general nature of processes taking place in sectors where the manufacture of substances or production of mixtures takes place or processes with closed process conditions as applied in chemical industry[25]. The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge the system are not included.
PROC2	Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions	Describes the general nature of processes taking place in sectors where the manufacture of substances or production of mixtures takes place (continuous processes that involve limited manual interventions), or processes with equivalent closed process conditions as applied in chemical industry. The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge the system are not included.

[25] The equivalent conditions need to be described in the exposure scenario and the related exposure estimate should be associated with an explanation in the CSR. For further information, please see Chapter R.14 of the IR&CSA Guidance.

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



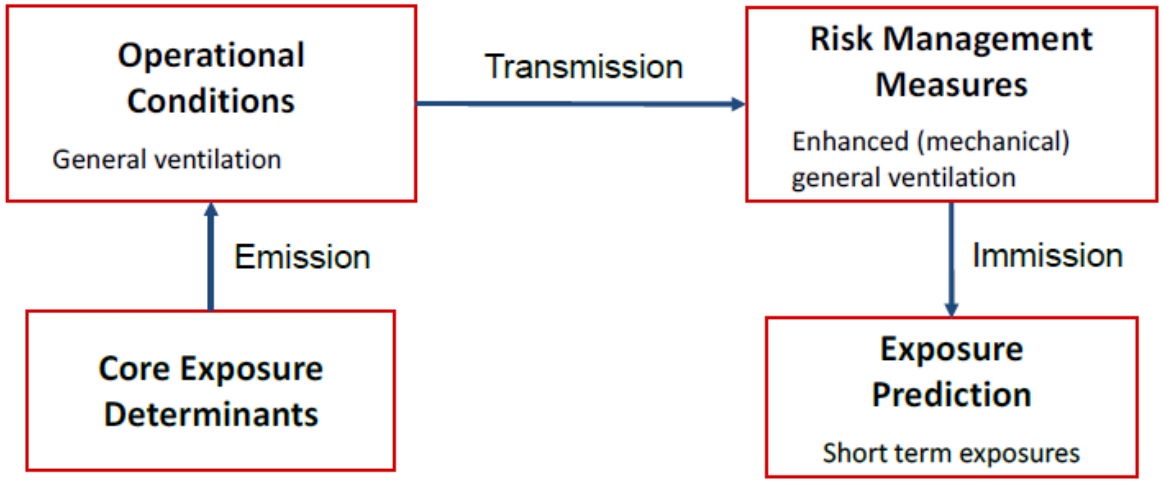
ECETOC TRA

APPENDIX A: RATIONALE FOR TRAv3 WORKER INHALATION PREDICTIONS

Table A-1: Rationale Behind TRAv3 Worker Exposure Predictions

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
1	Use in closed process, no likelihood of exposure	yes	High			n/a	n/a
	(solids)	no		0.01	0.1		
	mg/m³	yes	Moderate			n/a	n/a
		no		0.01	0.01		
		yes	Low			n/a	n/a
		no		0.01	0.01		
	(volatiles)	yes	High			n/a	n/a
	ppm	no		0.01	0.1		
		yes	Moderate			n/a	n/a
		no		0.01	0.01		
		yes	Low			n/a	n/a
		no		0.01	0.01		
		yes	Very Low			n/a	n/a
		no		0.01	0.01		
2	Use in closed, continuous process with occasional controlled exposure	yes	High			90	80
	(solids)	no		1	5		
	mg/m³	yes	Moderate			90	80
		no		0.5	1		
		yes	Low			90	80
		no		0.01	0.01		
	(volatiles)	yes	High			90	80
	ppm	no		25	50		
		yes	Moderate			90	80
		no		5	20		
		yes	Low			90	80
		no		1	5		
		yes	Very Low			90	80
		no		0.1	0.1		
3	Use in closed batch process (synthesis or formulation)	yes	High			90	80
	(solids)	no		1	5		
	mg/m³	yes	Moderate			90	80
		no		1	1		
		yes	Low			90	80
		no		0.1	0.1		

Exposure – input parameters



Source: ECETOC TRA version 3- Background and Rationale. Technical Report No. 114. July 2012.

Inhalation exposure

Parameters:

1. **PROCs** : in REACH (for registered chemicals)
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

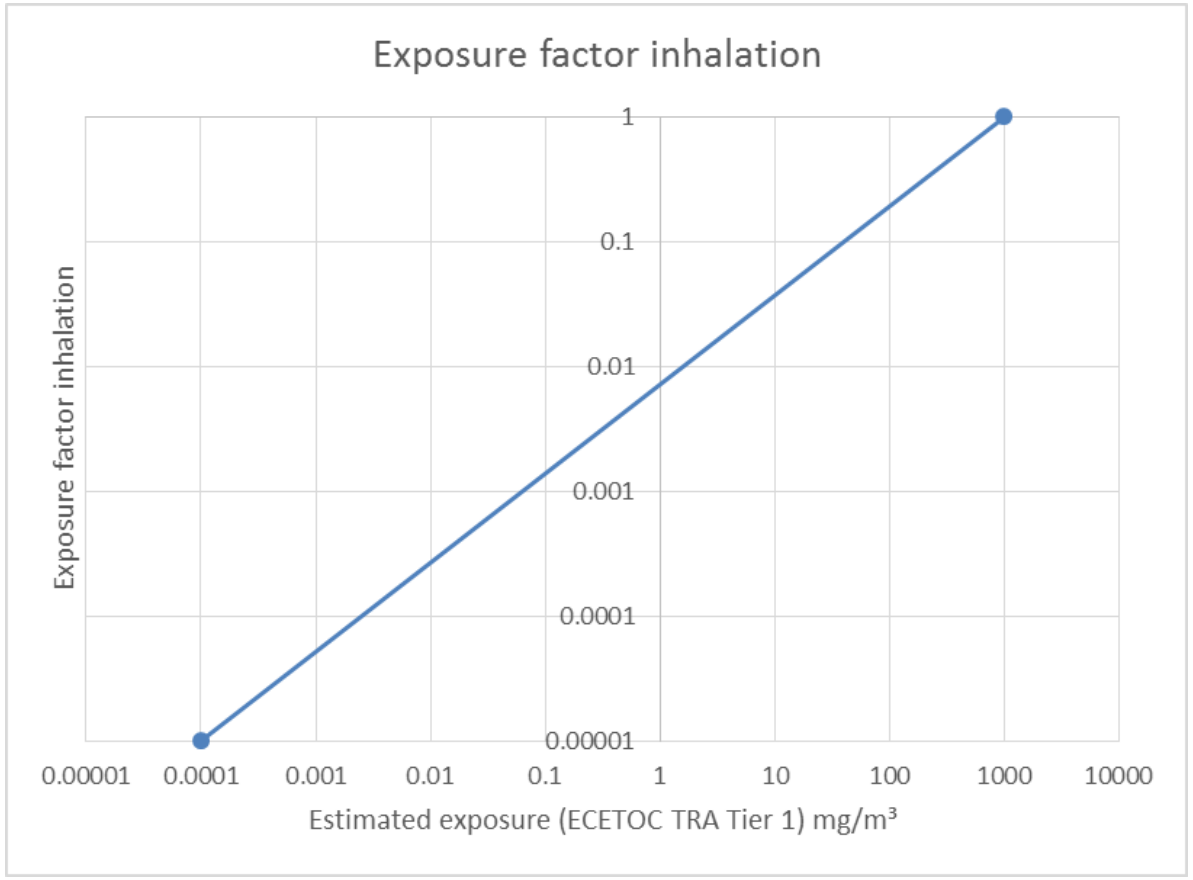
Dermal exposure

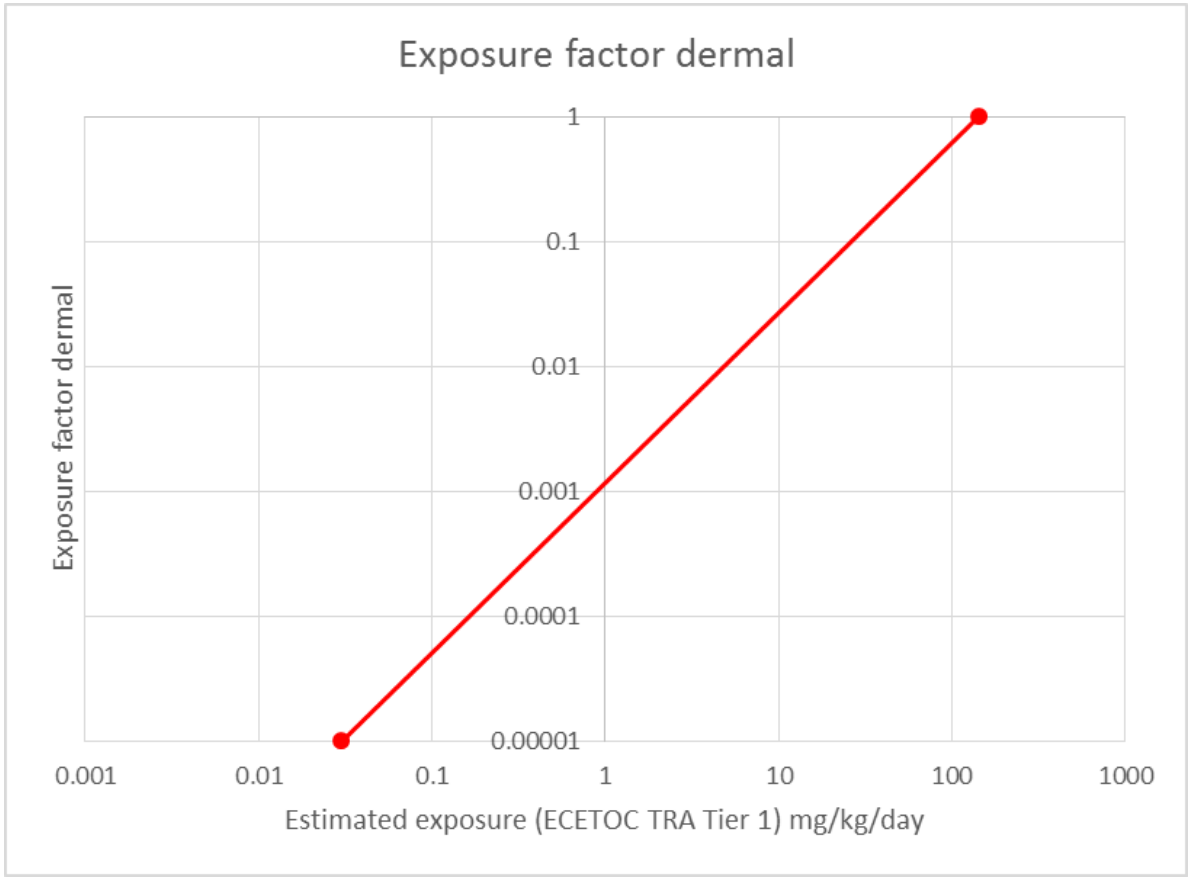
derived from PROCs and Use (parameters 1 and 2 above)

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 HBCD: 6.3 x 10-5	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 exposure concentration from ECETOC TRA into ProScale exposure concentration factor (ECF)





PHF

Person-Hours Factor

Number of person-hours of exposure per mass unit of produced product

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)

ProScale

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**

MF

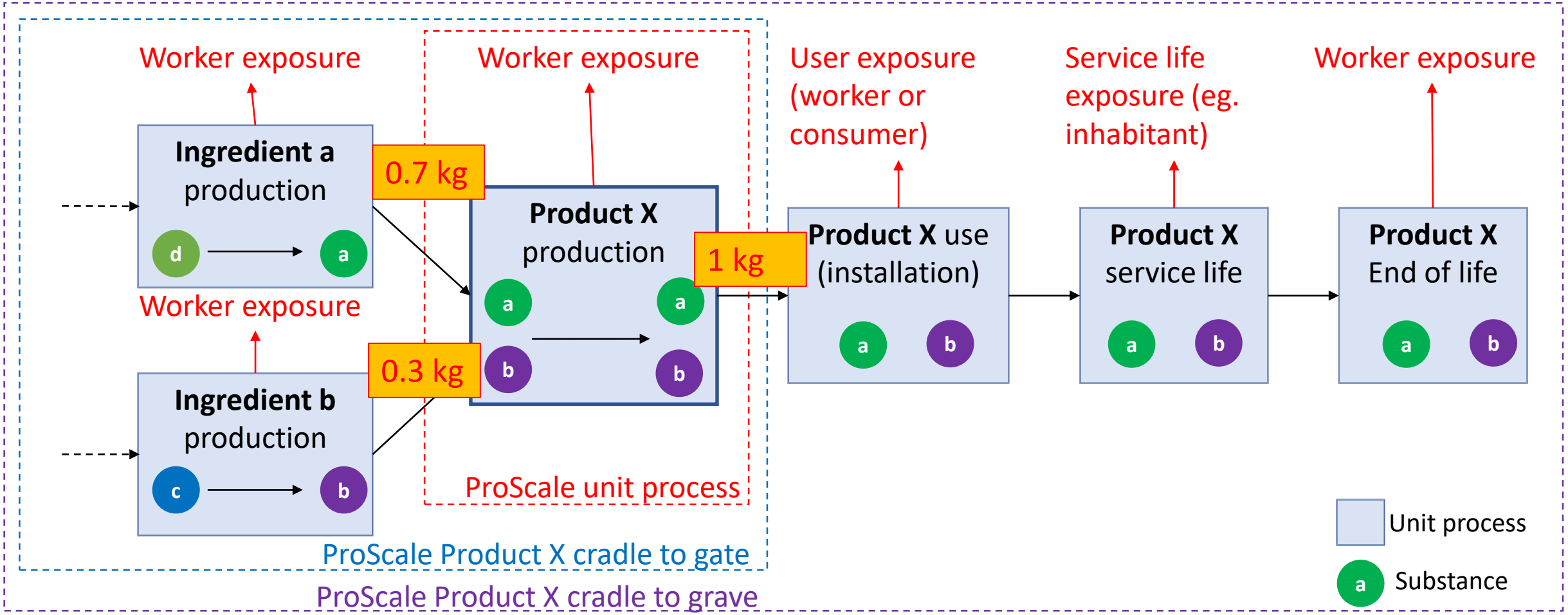
Mass Flow

The amount of substance used per functional unit

Conceptual life cycle & ProScale

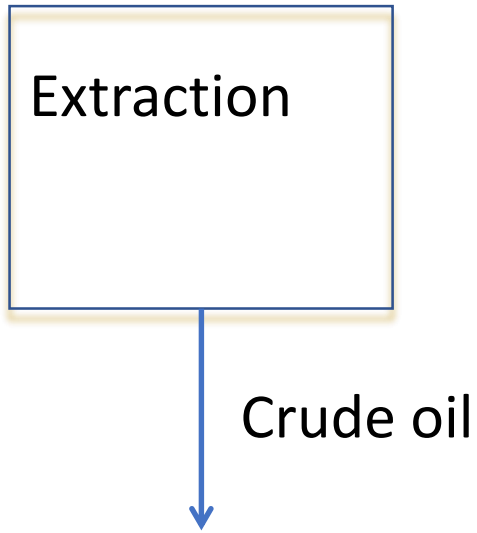
MF
Mass Flow

The amount of substance used per functional unit



PSU - ProScale Score for Unit Process

Example: PSU for crude oil (simplified)



- 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)

- **PSU (crude oil extr) = 100000 * 0.07 * 0.0004 * 1 = 2.8** (per kg crude oil)

Thank you !

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FORMAS

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