ProScale Conference

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

Brussels, 5 October 2017 Hôtel Métropole 9.30 to 17.00

WELCOME!



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 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	



ProScale Conference

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

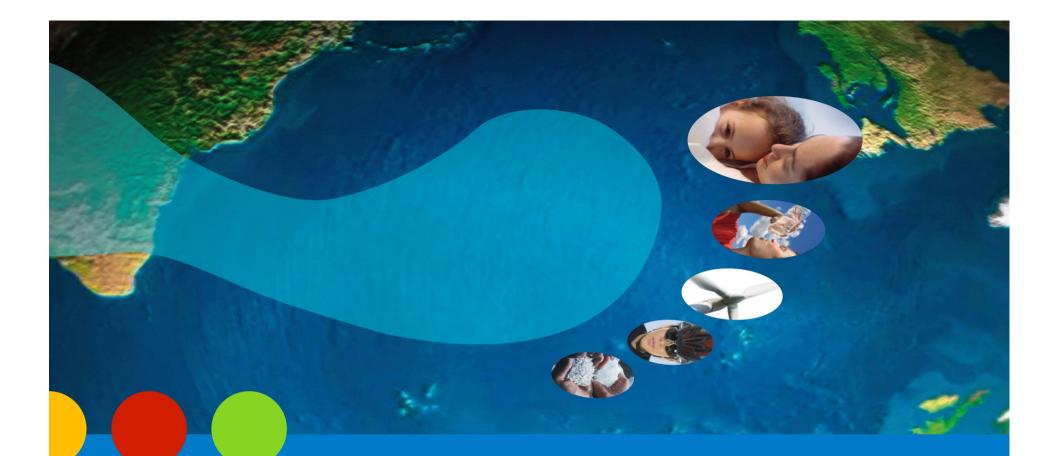
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Reconciling RA and LCA

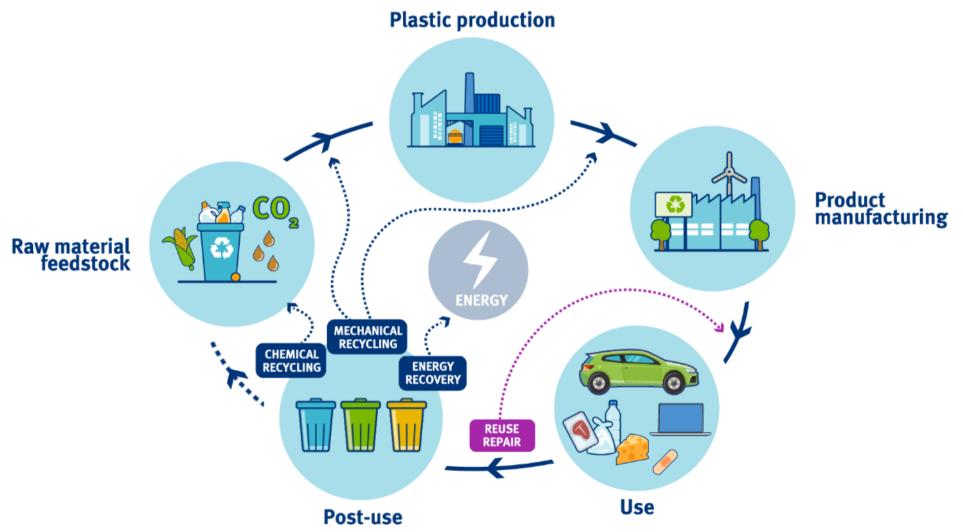
Proscale Conference, Brussels, 5 October 2017

Guy Castelan



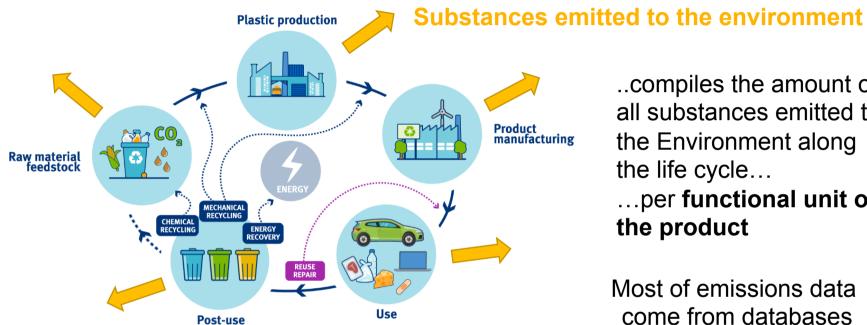
Let's think life cycle...





The Life Cycle Inventory phase...





..compiles the amount of all substances emitted to the Environment along the life cycle...

...per functional unit of the product

Most of emissions data come from databases

Result of LCI

Outputs				
Type Of Flow	Classification	Flow	Variable	Resulting amount
Product flow	Valuable substances / Materials / Plastics	Polystyrene granulate (PS)		1.0 kg (Mass)
Product flow	Deposited goods / Radioactive waste	Highly radioactive waste		8.25964E-7 kg (Mass)
Product flow	Deposited goods / Radioactive waste	Low radioactive wastes		1.02404E-5 kg (Mass)
Product flow	Deposited goods / Radioactive waste	Medium and low radioactive wastes		4.83542E-6 kg (Mass)
Product flow	Deposited goods / Radioactive waste	Radioactive tailings		5.34489E-4 kg (Mass)
Elementary flow	Emissions / Emissions to air / Emissions to air, unspecified	1,2,4-trimethylbenzene		4.77301E-17 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	1,2-dibromoethane		1.97856E-17 kg (Mass)
Elementary flow	Emissions / Emissions to air / Emissions to air, unspecified	1,2-dichloroethane		2.88625E-16 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	1,2-dichloroethane		4.48745E-18 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	1,2-dichloropropane		3.81433E-19 kg (Mass)
Elementary flow	Emissions / Emissions to air / Emissions to air, unspecified	2,3,7,8-tetrachlorodibenzo-p-dioxin		1.36825E-14 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	2,3,7,8-tetrachlorodibenzo-p-dioxin		9.81369E-19 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to sea water	acenaphthene		1.40149E-9 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	acenaphthene		3.22457E-10 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to sea water	acenaphthylene		5.77656E-10 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	acenaphthylene		1.31654E-10 kg (Mass)
Elementary flow	Emissions / Emissions to air / Emissions to air, unspecified	acetaldehyde		1.17488E-6 kg (Mass)
Elementary flow	Emissions / Emissions to air / Emissions to air, unspecified	acetic acid		5.37939E-6 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	acetic acid		2.42959E-10 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to sea water	acetic acid		6.11925E-14 kg (Mass)
Elementary flow	Emissions / Emissions to air / Emissions to air, unspecified	acetone		1.17004E-6 kg (Mass)
Elementary flow	Emissions / Emissions to air / Emissions to air, unspecified	acid (as H+)		7.96355E-11 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	acid (as H+)		3.69853E-9 kg (Mass)
Elementary flow	Emissions / Emissions to air / Emissions to air, unspecified	acrolein		5.61972E-10 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	acryolonitrile		2.39671E-15 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to sea water	adsorbable organic halogen compounds		7.03021E-13 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	adsorbable organic halogen compounds		9.85244E-7 kg (Mass)
Elementary flow	Emissions / Emissions to air / Emissions to air, unspecified	aluminium		1.49922E-10 kg (Mass)
Elementary flow	Emissions / Emissions to soil / Emissions to non-agricultural soil	aluminium		3.58767E-9 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	aluminium		9.23084E-5 kg (Mass)

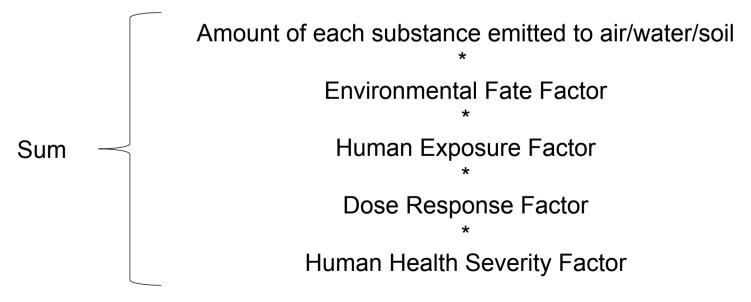
Life Cycle Analysis



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lementary flow	Emissions / Emissions to soil / Emissions to non-agricultural soil	ammonia	7.27379E-8 kg (Mass)
lementary flow	Emissions / Emissions to water / Emissions to sea water	ammonia	2.44728E-11 kg (Mass)
lementary flow	Emissions / Emissions to water / Emissions to fresh water	ammonia	3.0563E-5 kg (Mass)
lementary flow	Emissions / Emissions to air / Emissions to air, unspecified	ammonium	1.48784E-10 kg (Mass)
Elementary flow	Emissions / Emissions to water / Emissions to fresh water	ammonium	7.20484E-14 kg (Mass)
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Tox and ecotox impact assessment model is applied on this whole list

USETOX



LCA (eco) tox indicator



• It does not (want to) say if the product is safe

- It is potential emissions and impacts (most of data comes from generic database)
- The inventory is built relative to the functional unit and does not say how much a worker, a user... is exposed to a substance and how much exposure is admissible
- Interesting to
 - Priorize substances in the result of inventory
 - Address Hot-Spot
- Is it mature for comparison of products ?
 - > Interprete with prudence
 - > Take care of artefacts from database

PlasticsEurope So how do we know about safety ? Association of Plastics Manufacturers Is it safe for workers? for neighbourhood? for the environment? **Plastic production** Product manufacturing Raw material feedstock MECHANICAL RECYCLING CHEMICAL RECYCLING ENERGY RECOVERY REUSE REPAIR Is it safe for consumers ? Use Post-use

Answering these questions uses Risk Assessment



- Risk is a function of HAZARD and EXPOSURE to a substance
- HAZARD is an intrinsic property of a substance
- EXPOSURE to a substance is assessed from the perspective of the exposed category
 - Workers
 - Consumers
 - Environment...
 - taking into account the context of application, protection measure, physicochemical properties...
- For a given susbtance risk is characterised by comparing the estimated exposure to the maximum admitted exposure

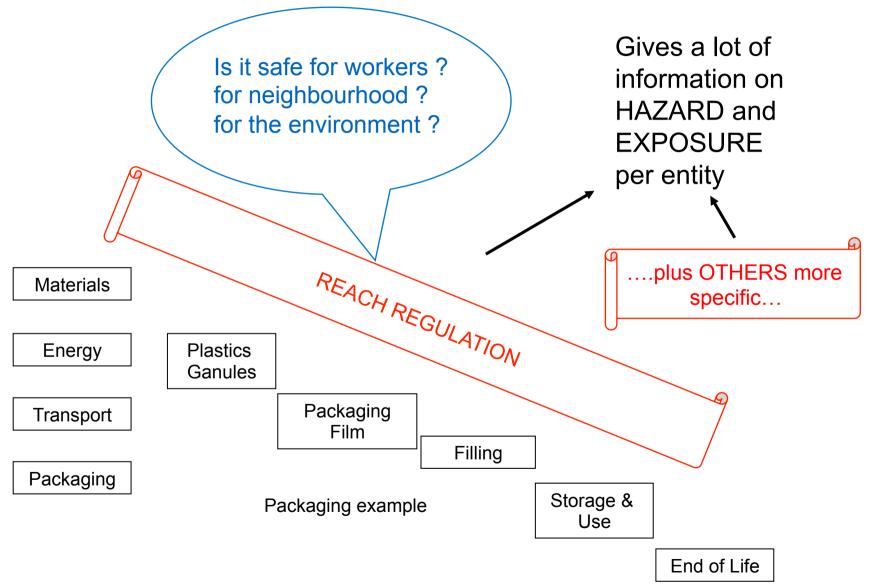


• The way RA is done is framed by REGULATION

• The acceptable level of risk is given by REGULATION

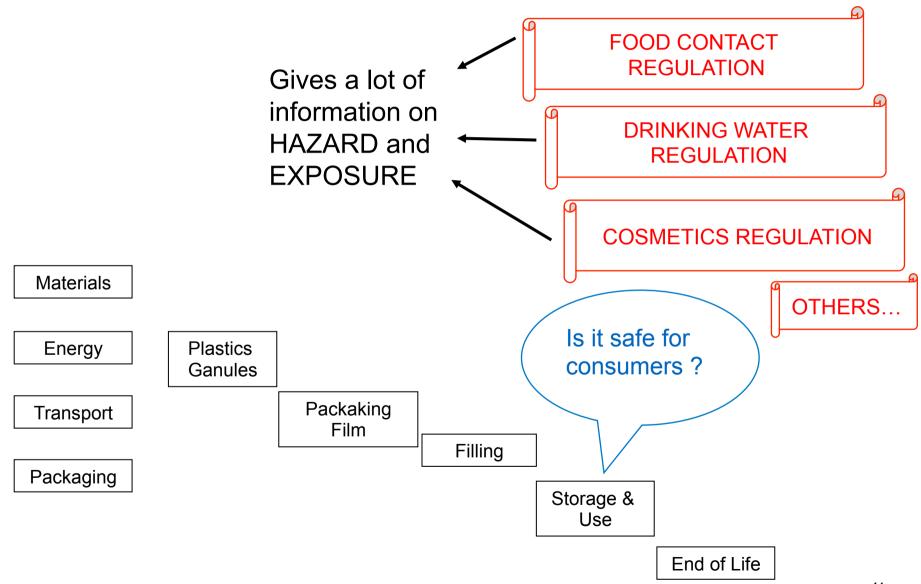
EU Regulations along life cycles





EU Regulations along life cycles



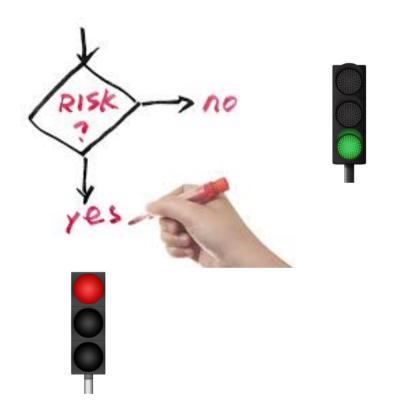


Risk Management



• RA is instructed

for a **PASS/FAIL...**



...but this knowledge could be exploited further



There is a demand to reduce hazard and exposure of products

- Along with the environmental performance where LCA is acknowledged
- Beyond compliance with regulation

Proscale uses the strength of each method

• Life Cycle perspective of products

• Abundance of information on risk brought by REACH

to compare hazard and exposure along the life cycle of products

A chance to improve products basing on a risk metric

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THE ProScale[™] METHOD – AN INTRODUCTION

TOMAS RYDBERG, IVL

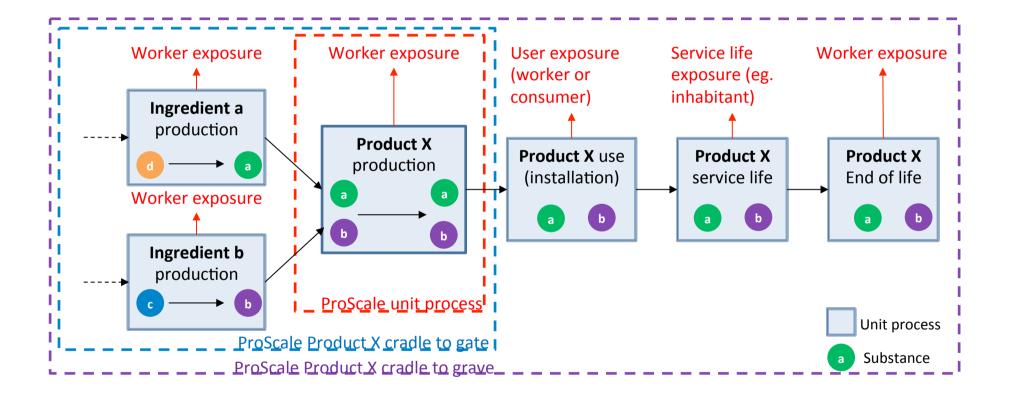


Background

- 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-tocustomer communication.
- Complementary to other approaches
 - As a minimum suitable for "Additional information",
 - As "LCA compatible" as possible
- Use existing data
 - e.g. REACH based

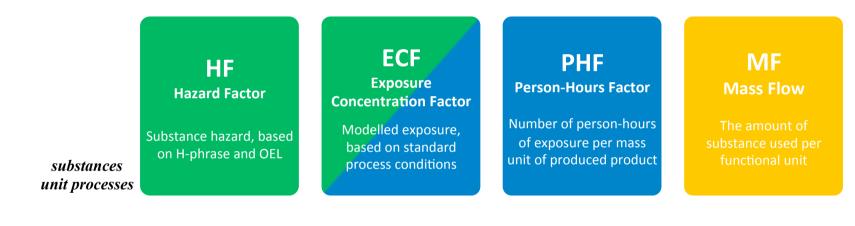


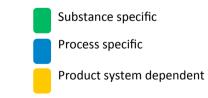
Conceptual life cycle & ProScale





Elements of ProScale – schematic presentation

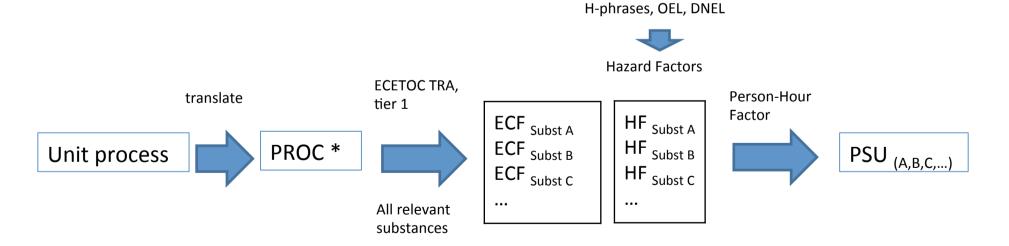






PSU - ProScale Score for Unit Process

- 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



Hazard Factor



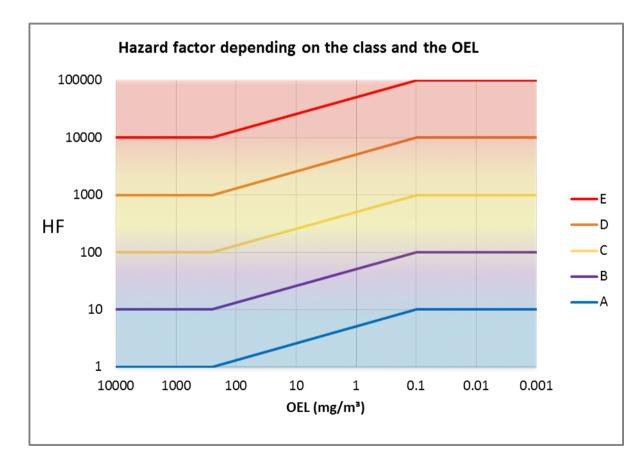
• H-phrases have been grouped in five ProScale hazard classes

H-phrases · classification ·

- 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
В 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



- 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".



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

тм

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

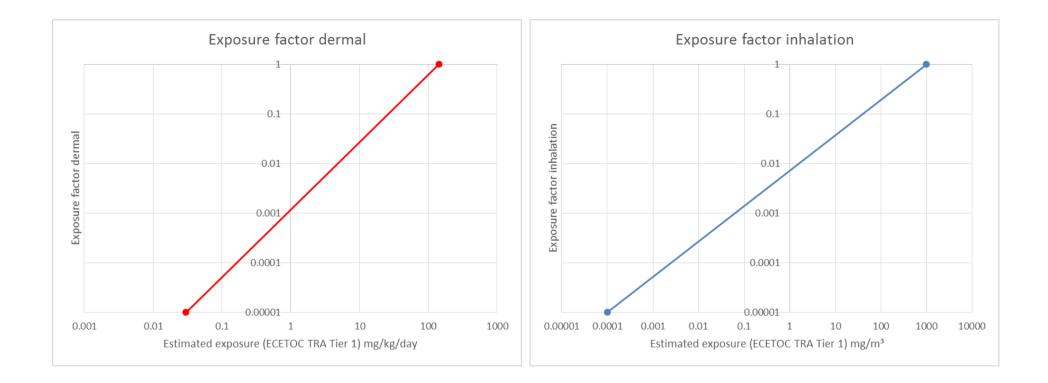


Exposure – example of significance of PROC selection and fugacity level Initial exposure value (mg/m³), (no RMM)

			Fugacity l	evel, fluids	
		negligible	low	medium	high
Vapo	ur press.		>=0.00001-		
range	es	< 0.00001	<0.5	0.5 to 10	>10
Exam	ple				
substances			DEHP: 0.001	Styrene: 0.67	Hexane: 17
	1	0.01	0.01	0.01	0.01
PROC	4	0.1	5	20	100
РР	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

 $Person - Hour Factor(industrial processes)[hr/kg] = \frac{Annual hours worked \left[\frac{hr}{year}\right]}{Annual production volume \left[\frac{kg}{year}\right]}$ $Person - Hour Factor(installation)[hr/kg] = \frac{Exposure duration [hr]}{Amount of product used [kg]}$ Europeane duration [hr]

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

- 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	t 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
Pro Cor	Scale Iference

Example – Crude oil extraction



Step-by-step

	• Assign PROC => PROC 2 (for illustration)
Extraction	 Substance(s): crude oil
	 Establish HF
	 H-phrase H350 => ProScale class E
	 OEL => not found => ProScale HF = 100000 (highest in class)
	 Establish ECF
Crude oil	 Volatile: Vapour pressure 55.25 kPa => "high"
	RMMs: No
V	 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

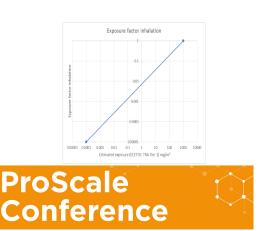


Exposure concentration Factor – Service Life

• 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/m²h) can be either measured or modelled
 - Example: SER for DEHP from PVC flooring = $0.4 \,\mu g/m^2h$ (literature)
- Steady-state concentration= $0.4*12/15 = 4.8/15 = 0.32 \,\mu g/m^3$
- ECF is achieved 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} ≈ 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, has OEL) => HF = 1.38×10^4 ullet

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





Tomas Rydberg, tomas.rydberg@ivl.se

THANK YOU FOR YOUR ATTENTION



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APPLICATION OF PROSCALE[™] – HUMAN TOXICITY POTENTIALS OF SPECIFIC PRODUCT SYSTEMS

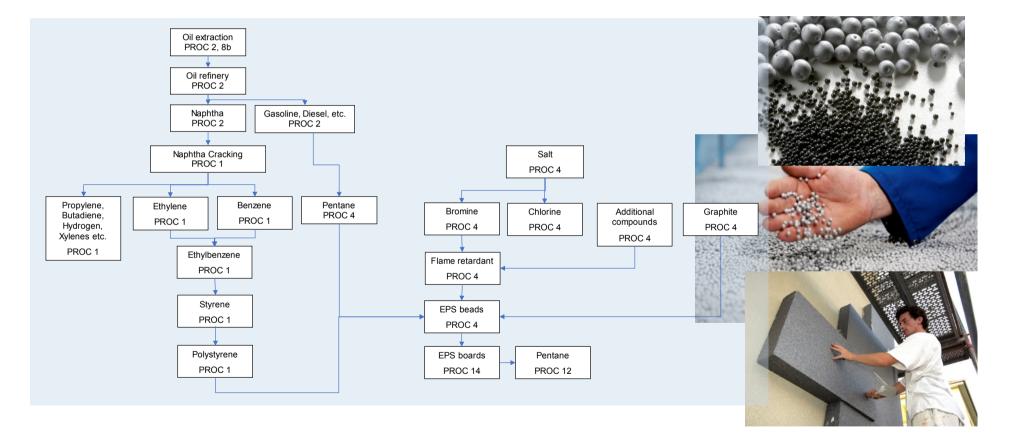




Martin Glöckner, Deutsche Bauchemie

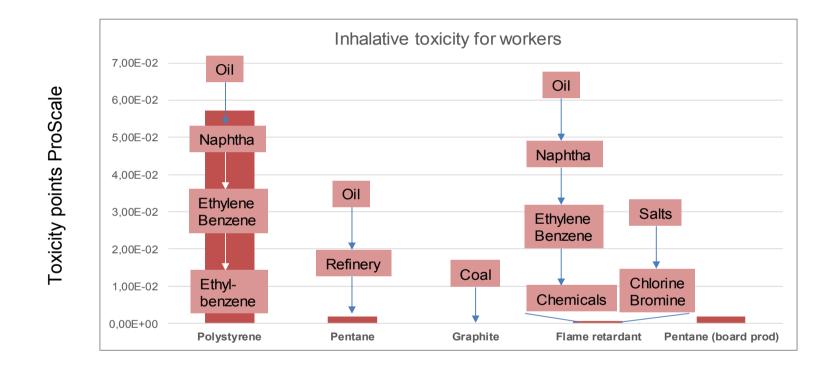
Peter Saling, BASF SE

ProScaleTM example EPS insulation board – system boundaries from cradle-to-gate





Scope of the ProScaleTM test case Results EPS boards for different compounds



Highest contribution

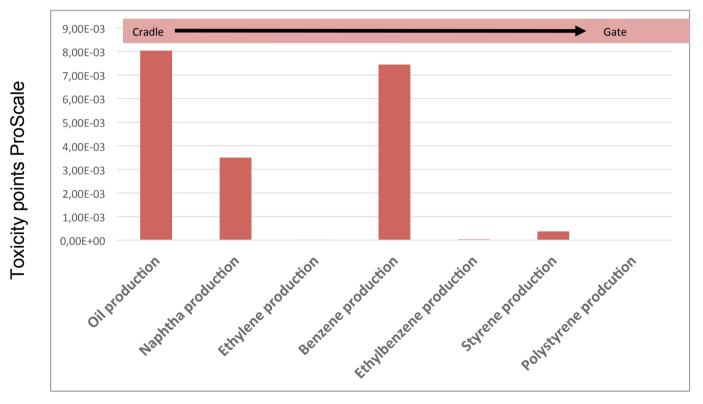
- Polystyrene via naphtha upstream calculation
- Flame retardant bromine production
- Pentane exposure in the blowing process

All products assessed as cradle to gate with mass flows, the total is the EPS board system

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Scope of the ProScale[™] test case

Contribution of the substances to the process (EPS board production) + the upstream part; Inhalative toxicity for workers



Highest contribution

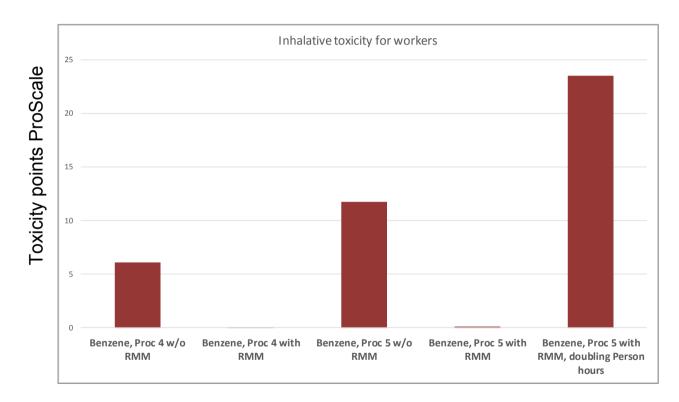
- Oil production as basis for all petrochemical products
- Benzene with H350, H340 classification
- Naphtha production with H350, H340 classification

Low contribution

- Ethylene with H220, H336 ...
- Styrene with H226, H332, H 315 ...



Scope of the ProScaleTM test case Scenarios and variations of ProScale results of benzene

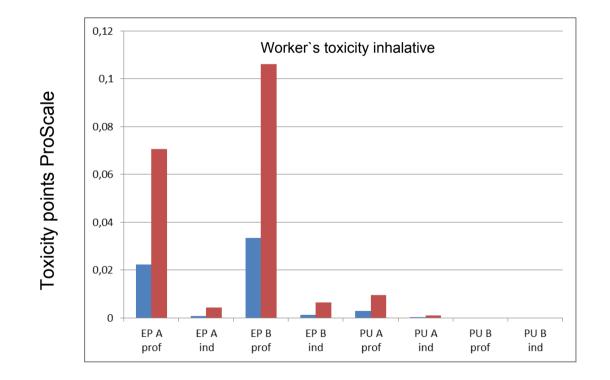


- Person hours can influence the result significantly
- The selection of the PROC is important
- RMM needs to be selected carefully
- ProScale distinguishes between different reaction conditions



Test case *"Construction Chemicals"*

Comparison of professional (time factor 0,2) and industrial (time factor 0,02) settings, PROC 5



- Significant differences between "Industrial" and "Professional" via time factor and RMM
- Important impacts by materials in the mixtures

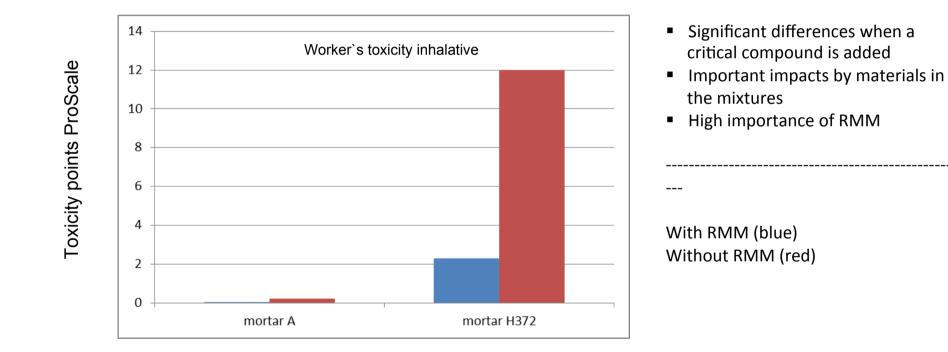
EP = epoxy-based; PU = polyurethane-based

With RMM (blue) Without RMM (red)



Test case "Construction Chemicals"

Sensitivity check regarding H372 component (5% crystalline silica flour), PROC 5, professional





Application and use of ProScaleTM Results

- The ProScale scores (PSS) for the defined formulations and relevant activities can be calculated for products including all upstream steps in an "easy-to-use" approach, relying on existing and easily available data (H-phrases, OEL,...)
- The results of the ProScale score calculations show which products, substances and life cycle steps have high contributions.
- Inhalative results are much more significant than dermal. Oral is not important for workers
- Changes of vapor pressure, RMM or PROC have significant influences to the result
- The system is sensible for changing time factors, material flows and changes from industrial worker to professional worker.
- Results are meaningful and useful.



Peter Saling, peter.saling@basf.com

Martin Glöckner

THANK YOU FOR THE ATTENTION



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ProScale[™] TEST CASE EXAMPLES & OBSERVATIONS



Tomas Rydberg, IVL Ivana Dencic, Corbion

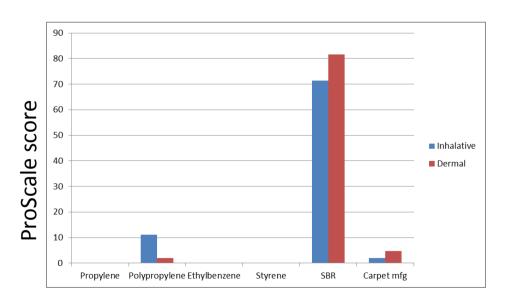
ProScale[™] TEST CASE EXAMPLES & OBSERVATIONS



Case study: carpet System boundary cradle to gate



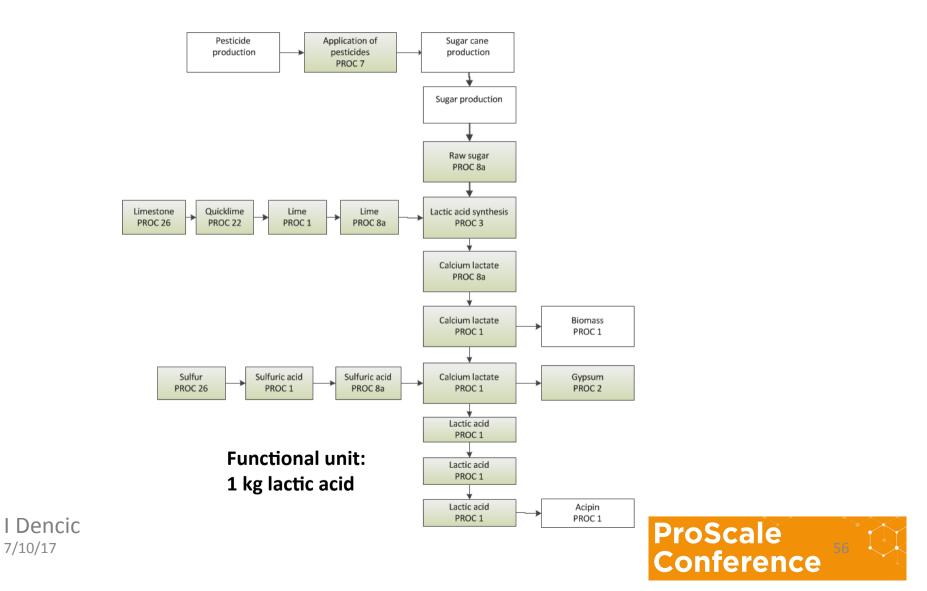
Composition:		
PP : SBR Total:	2.4 kg 2.8 kg 5.2 kg	



Adapted from: Baradaran, B: Toxicological Exposure Assessment of Carpet Manufacturing with ProScale Method, M.Sc. Thesis, Uppsala Univrsity & IVL, 2017



Case study: lactic acid System boundary cradle to gate



Assumptions

Sugar manufacturing

- spraying of pesticides; herbicides 2 kg/ha, insecticides 7.5 kg/ha (*source: Agrifootprint V*2).
- Application 2 ha/h

Lime manufacturing

• limestone mining, calcination, lime production

Sulfuric acid manufacturing

- sulfur mining, SO2 and SO3 production, H_2SO_4 production

Lactic acid process*

- 100 kT/y
- 90 % fermentation yield

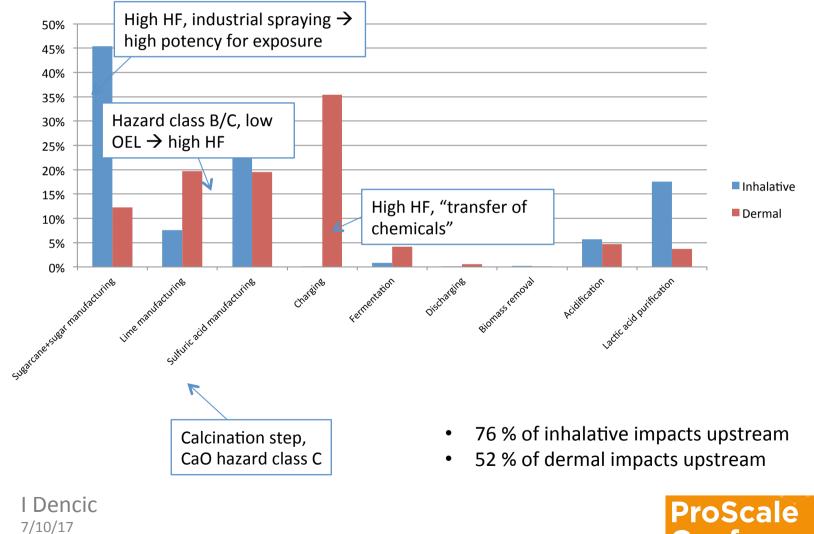
Assumptions for exposure scenario:

- Core process: indoors with LEV, no RP, no PPE*
- Pesticide spraying: no LEV, 95 % RP, gloves APF 10
- Lime and sulfuric acid production: limestone and sulfur mining with RP and gloves APF 20, calcination gloves APF10, the rest as lactic acid

I Dencic 7/10/17 *study example, does not represent Corbion's process

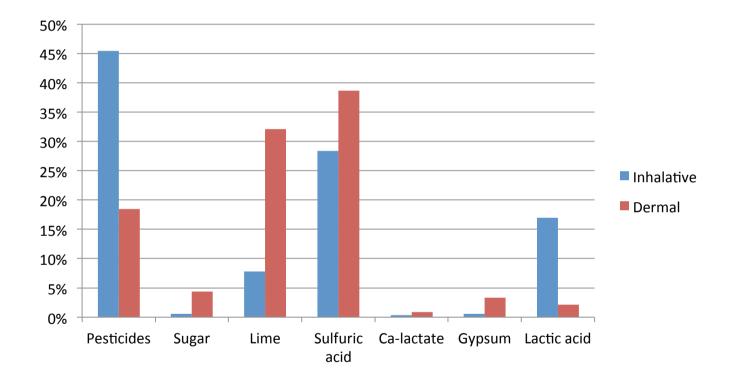


ProScale scores (cradle-to-gate) Breakdown per process units



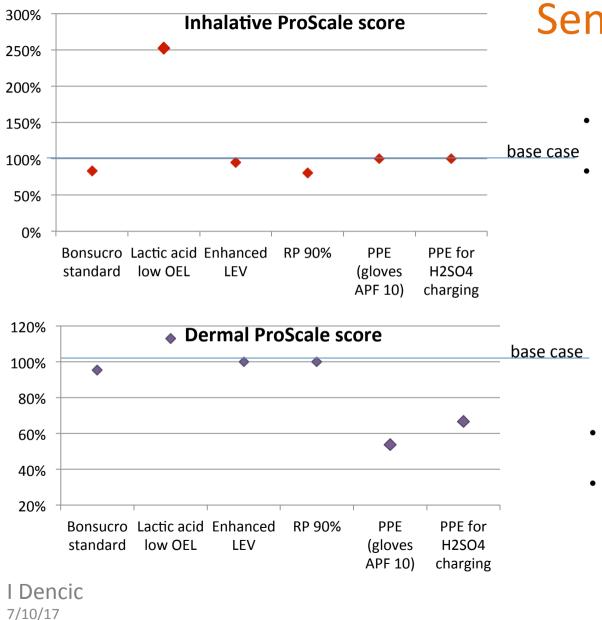


ProScale scores (cradle-to-gate) Breakdown per chemical





I Dencic 7/10/17



Sensitivity study

- Bonsucro standard: 17 % reduction in inhalative score
 OEL is an important
 - parameter

- High sensitivity on the type of PPE: 50 % reduction
- PPE for H2SO4 charging!



Observations

- The method provides a good insight into human toxicity along the life cycle of the lactic acid
- Easy to use template, clear guidance document
- H-phrases and OEL databases can be improved
- Surprisingly high sensitivity on the type/use of PPE
- **PHF** assumes continuous direct exposure of workers?
- Lactic acid has hazard class C, no established OEL value. Selecting HF = 100 or HF = 1000 has a high impact on the total score
- Uncertain parameters: upstream RMM, FTEs and PHF default values suggested, however impact can be high
- **PROCs**: no differentiation between different process conditions?
- Allocation method not fully consistent with LCA ISO guidance where suggestion is to apply system expansion with substitution rather than allocation
- By products (biomass, acipin) could not be considered no HF and OEL defined



I Dencic 7/10/17

Ivana Dencic, ivana.dencic@corbion.com

Tomas Rydberg, tomas.rydberg@ivl.se

THANK YOU FOR YOUR ATTENTION



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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 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	
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AFTERNOON PROGRAMME

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Workshop A <i>(Langevin)</i>	ProScale in practice – method & tool use	Peter Saling, BASF Andreas Bednarz, Covestro
Workshop B (<i>Rubinstein</i>)	Applying the same principles to ecotoxicity and human toxicity via the environment?	Quentin de Hults, BASF Frédéric Palais, Solvay
Workshop C <i>(Einstein)</i>	Implementing ProScale in different value chains – priorities & requirements	Martin Gloeckner, Deutsche Bauchemie Alain Wathelet, Solvay
15:15-15:35	Echoes from workshops B & C	
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Echoes from Workshop C – Implementation in value chains

- Sectors with interest
 - Buy-in of the method by the business/market
 - Question: interest for the final consumer?
 - Construction/building (with Government push ...)
 - Food (through EPD) ?
 - Detergent ? \rightarrow mostly interested by Ecotox
 - Textile ? (probably not...)



Echoes from Workshop C – Implementation in value chains (ct'd)

- Easiness: « simple » ProScale scores
- Data needed (for communication with reliability)
 - Via ecoprofile program for chemicals
 - Via producers association
 - Via existing databases (Gabi, Ecoinvent, ...)
- Hot-spot analysis in the supply chain



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IMPLEMENTATION & FUTURE OF THE PROSCALE METHOD



Commitment

All ProScale consortium partners are committed to

- using ProScale and sharing experience,
- providing primary data (OEL, H-phrases, vapour pressure) for the database
- developing basic ProScale data for generic chemicals and making them available in the database



Towards a ProScale users' community

The ProScale method will be handed over to a <u>hosting organisation</u> that will

- Be a not for profit organisation
- Be the *first contact point* for users and provide a *ProScale Helpdesk*
- *Consult* consortium partners on difficult methodological questions
- Manage database and free access tool
- Develop a *self-funding model* for this work



What's next?

- The ProScale method is there to be used, shared, developed
- The database is there to be populated

Let's do this together!



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THANK YOU!

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