

**International Workshop: Consequences of REACH  
for other legal and administrative environmental instruments**  
*Evaluating the Environmental Effectiveness of REACH (REACH:EEE)*  
October 11 & 12, 2007 Berlin

## Working group 2: Immission related strategic issues

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# Overview

**Aim of the discussion in the working group**

**Part 1: REACH and the safe use of chemicals.**

**“New” substance-related information.**

**Part 2: PNECs / DNELs as indicator values.**

**The monitoring of risk reduction measures.**

**Discussion issues, conclusions and recommendations**

# Aims of the discussion in the working group

Get a common understanding on

- specific “reference values” generated by REACH for the description of the safe use of chemicals;
- the relation between these values and existing environmental reference values;
- possibilities for enterprises and authorities to use this information for the monitoring of risk reduction measurements;

Develop conclusions and recommendations for

- the implementation of an immission-based monitoring;
- the cooperation between authorities on the European level;
- the cooperation between authorities and enterprises.

# Part 1: REACH and the safe use of chemicals. “New” substance-related information.

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**REACH and the safe use of chemicals**

**The Chemical Safety Assessment**

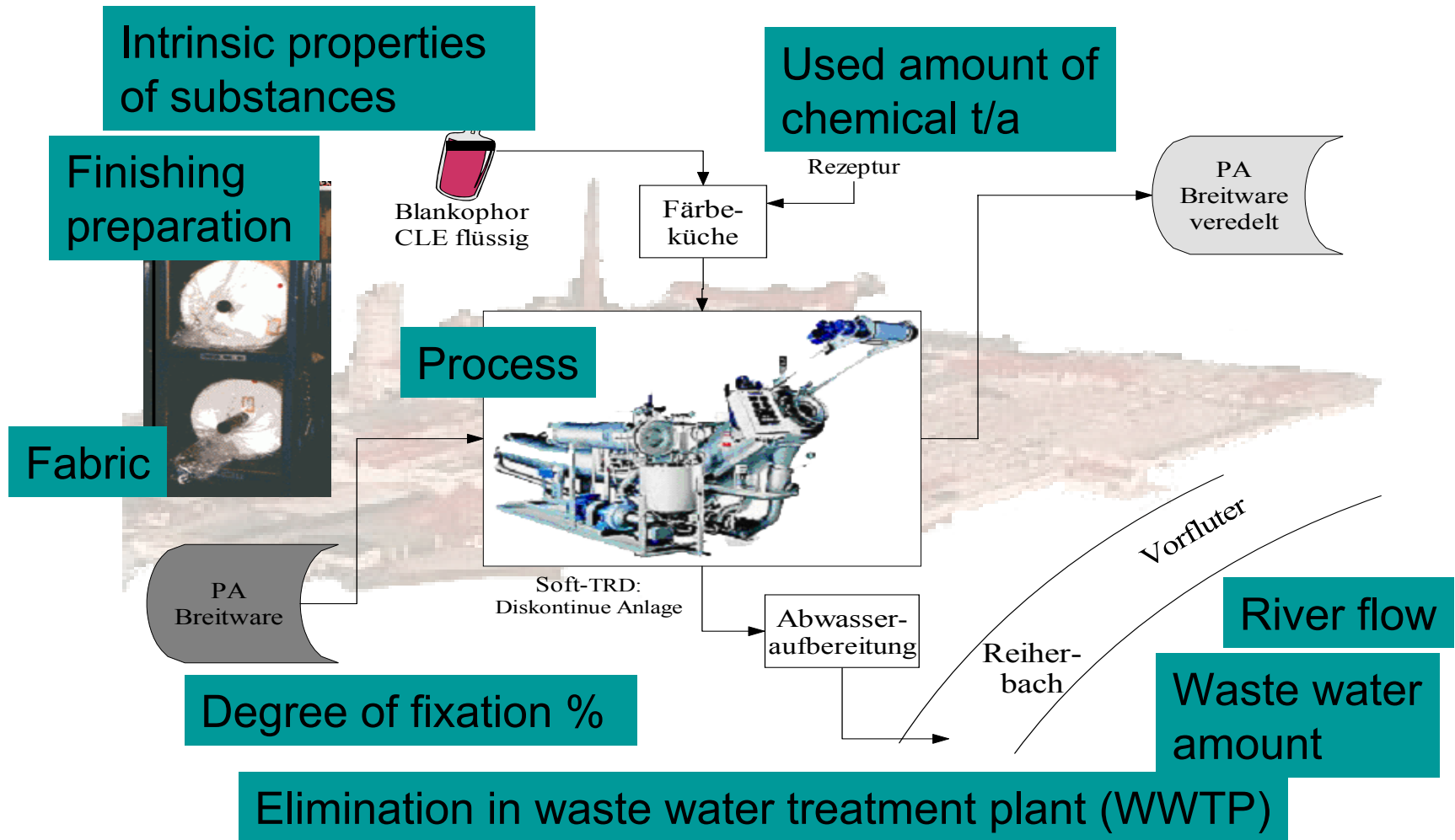
**PNECs, DNELs and related values**

**PBT / vPvB – assessment: non-threshold substances**

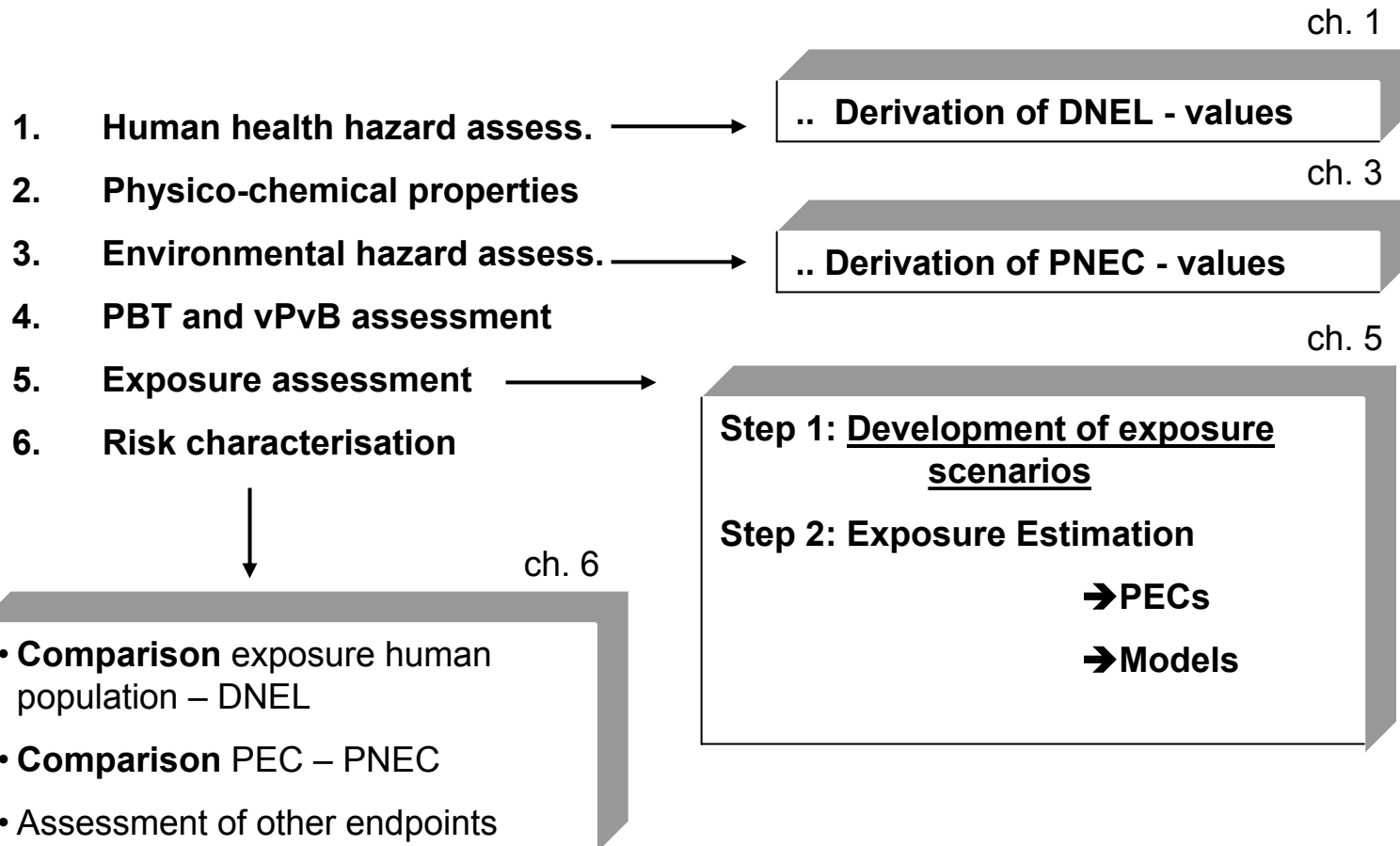
**Exposure Scenarios**

**What can we expect? And when? —→ Time line for new information**

# REACH and the safe use of chemicals

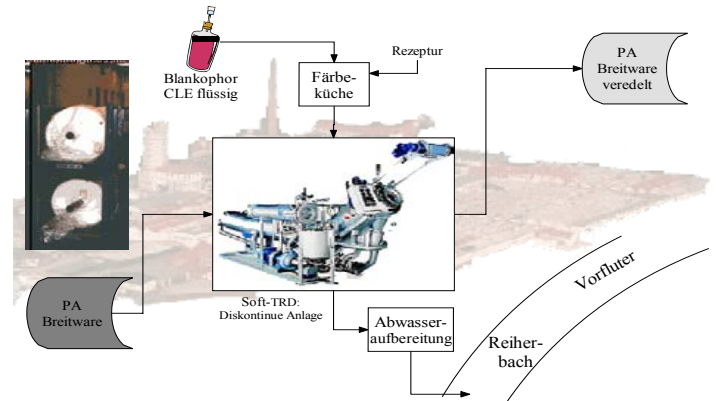


# Chemical Safety Assessment (CSA)



Generic standard exposure scenarios  
can cover **hundreds** of similar  
exposure situations

Example:



**Environmental Standard-Exposure-Scenario**  
for substances in dye stuffs and textile finishing chemicals  
for registration under the REACH system

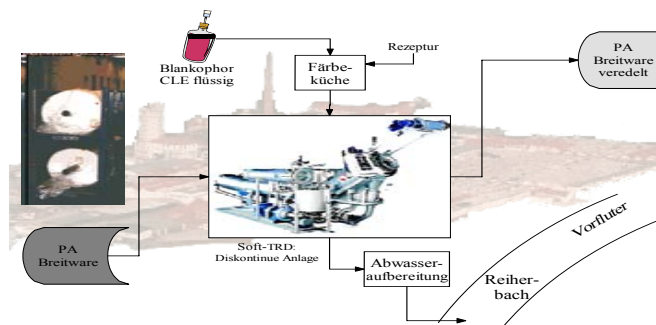
R+D project sponsored by the German Federal Environmental Agency (UBA); FKZ:  
202 67 433

contact: UBA Berlin, Birgit Müller

# Drivers in the Exposure Scenario

## Textile finishing - Waste water

**“Standard Finisher”**



Amount of substance per day a users level	150 kg/d	✓	15 kg/d
Share not fixed to fibre	100 %	✓	30 %
Biodegradation in WWTP	0 %	✓	85 %
Adsorption to Sludge	0 %	✓	0 %
Receiving water volume	20.000 m <sup>3</sup> /d	✓	2 Mio. m <sup>3</sup> /d
	↓		↓
PEC <sub>water, local</sub>	7.500 µg/l		0,34 µg/l
PNEC	←		←

Isophorone diamine (IPDA): risk-determining substance (RDS) for inhalation exposure in the 2-component adhesive used in flooring.

Substance	C (%)	$A_{\text{Safe}}$ ( $m^2$ )	$A_{\text{Safe}}/C$ $\times 100$
Bisphenol A DGE (700g/mol)	24.3	40	$1.6 \times 10^2$
Bisphenol F DGE	10.8	40	$3.7 \times 10^2$
IPDA	7.7	0.0028	<b>0.037</b>
m-phenylenebis (methylamine)	2.0	0.025	1.2

Lowest value  
of  $A_{\text{Safe}}/C$ ?

RDS: IPDA

$$A_{\text{Safe}} = \frac{DNEL}{C_{\text{Air}}} \times A_{\text{Room}} = \frac{0.06 \text{ mg} / \text{m}^3}{840 \text{ mg} / \text{m}^3} \times 40 \text{ m}^2 = 0.0029 \text{ m}^2$$

## RIP 3.2-2, Task IV: Structure of an exposure scenario

<b>1</b>	<b>Short title</b>
<b>2</b>	<b>Description of activities/processes covered</b>
<b>3</b>	<b>Operational conditions</b>
<b>4</b>	<b>Physical form of substance or preparation</b>
<b>5</b>	<b>Product specifications</b>
<b>6</b>	<b>Recommended Risk Management Measures</b>
<b>7</b>	<b>Waste related measures</b>
<b>8</b>	<b>a) Prediction of exposure    b) Derived control thresholds</b>
<b>9</b>	<b>Set of variables / link to calculation tool / compliance check methods</b>

RIP 3.2-2: Concise preliminary technical guidance document, Chapter D1, p.8 (May 2007)

# New information: Which? When?

## 30.265 Phase-in-Substances > 1t/a

• Production volume	• Number of substances *	• %	• Period for registration**	• Data requirements	
• 1-10 t/y	• 20.000	• 66	• 11 years	• Annex VII	
• 10-100 t/y	• 5.300	• 18	• 11 years	• Annex VIII	• CSA**
• 100 – 1.000 t/y	• 2.500	• 8	• 6 years	• Annex IX	• CSA
• > 1.000 t/y	• 2.465	• 8	• 3,5 years	• Annex X	• CSA

\* : estimated reduction (withdrawn / volume decrease): 5 – 15 %

\*\* : CMR (Kat 1 + 2) > 1 t/y: 3 years, R50-53 > 100t/y: 3 years

\*\*\*: CSA, for dangerous substances (Dir67/548/EEC) / PBT,vPvBs incl. EA and RC

ca. 70.000 existing substances < 1t/a

## Part 2: PNECs / DNELs as indicator values.

### The monitoring of risk reduction measures

For this part, additional information will be supplied during the workshop.

# Discussion issues, conclusions and recommendations

- **Identification of immission based strategic points of monitoring;**
- **Identification of interfaces between REACH and existing monitoring systems;**
- **Recommendation for an exchange of experiences from existing systems;**
- **Conclusions for the implementation of an immission based monitoring;**
- **Conclusions for the cooperation between authorities;**
- **Conclusions for the cooperation between enterprises and authorities.**

# Additional information to specific points

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## RIP 3.2-2, Task IV: Structure of an exposure scenario / details / 1

1	Short title: industry sector(s) / technical function / technical process / article type
2	Description of activities/processes covered
3	<b>Operational conditions: duration and frequency of use, maximum amount used per time</b> <b>Other operational conditions determining exposure:</b> <b>(1) Temperature;</b> <b>(2) Capacity of the receiving environment ( water flow; room size x ventilation rate);</b> <b>(3) Emission or release factors;</b> <b>(4) Conditions related to wearing and tearing (articles) / service-life time (articles).</b>
4	Physical form of substance or preparation

RIP 3.2-2: Concise preliminary technical guidance document, Chapter D1, p.8 (May 2007)

## RIP 3.2-2, Task IV: Structure of an exposure scenario / details / 2

5	Product specifications
6	Recommended Risk Management Measures
7	Waste related measures
8	<p>a) <b><u>Prediction of exposure</u></b> resulting from the conditions described above (3-6) and the substance properties (to be quantified based on exposure assessment in the CSA) make reference to the exposure assessment tool applied;</p> <p>b) <b><u>Derived control thresholds</u></b> (e.g. maximum emission, safe use amount, safe concentration in product, safe area to be coated) based on the exposure prediction under 8a.</p>
9	<p>Set of variables (and a suitable algorithm) which together indicate safe use, flexibility regarding the input values / may include a link to a suitable (easy-to-use) calculation tool</p> <p>Other methods to check compliance at DU level</p>

Modelling exposures: example textiles / clothing

Research Project: Textile auxiliaries and Human Exposure

BfR, IFOP, TEGEWA

$$D_i = RG \times TG \times EH \times MA \times KF \times \frac{PF}{KG}$$

Di: average internal dose

MA: migration factor

RG: remaining part on textile

KF: use factor

TG: textile weight

KG: body weight

EH: exposed area

PF: penetration factor