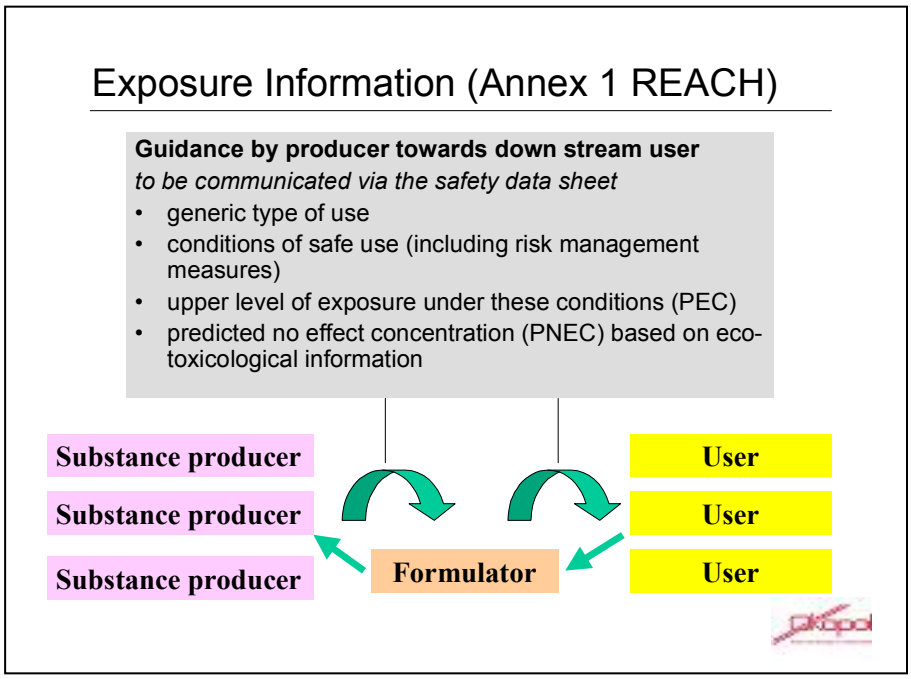
Environmental Standard-Exposure-Scenario for substances in dye stuffs and textile finishing chemicals for registration under the REACH system[1]

Interim Report (July 2004)

1. Background

Under the REACH system as proposed in the draft REACH regulation (October 2003) companies importing or producing and marketing of substances > 1/a are obliged to register these substances. For dangerous substances in annual volumes > 10 t/a a safety assessment (including exposure assessment) is required. The exposure assessment includes an exposure scenario (type and conditions of use) and a prediction of the level of exposure to be expected. The exposure assessment needs to cover all life cycle steps from manufacturing of the substance and formulation of the preparation down to the use of the preparation in manufacturing of articles and the service life of these articles. All environment compartments and human health shall be covered for each life cycle step. This paper is focussed on safety assessment related to the environment.



At least three stakeholders in the supply chain need to contribute information to the safety assessment.

- The substance producer provides information on
  - the substance properties (hazard and exposure relevant),
  - the general conditions of use he believes to be safe
  - and a comparison between the estimated level of exposure that could occur under these conditions and the level of exposure at which no adverse effects are anticipated to occur.

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

- The formulator provides information on
  - The percentage of dangerous substance in his preparation,
  - possibly more specific information on the type and conditions of use
  - and based on this possibly more specific emission factors and exposure estimates.
- The industrial user of the preparation contributes information on
  - daily amounts used at a certain site,
  - the capacity of the environment to dilute the emission
  - and possibly more specific information on the type and conditions of use.

Only a combination of all these information leads to a realistic safety assessment. However, practical implementation of such concept meets various challenges. Based on the experience gained in a REACH simulation carried out in North-Rhine-Westphalia[2] the difficulties can be summarised:

- The three actors in the chain do not use the same "language".
- Parts of the information are not meant to be disclosed towards suppliers or customers.
- The information need to be structured and processed in a way that the assessment can be done with minimal efforts in the majority of cases:
  - Broad categorisation of use and exposure patterns in order to allow for standard-phrases and to ensure sufficient flexibility for innovation with regard to types and conditions of use.
  - A tiered system that allows for sequential conclusion whether further or more detailed information is needed.
- A harmonised IT-system to generate and communicate the information across the EU market is needed.

In order to develop a workable system, a set of standard-exposure scenarios is needed, under which the great variety of use and exposure patterns in the market can be clustered. An example for a sector specific standard-scenario is outlined below.

2. Objectives of the current project

The current project aims to develop a sector specific standard-exposure scenario (including a tool for calculation of exposure concentration) for the use of dye stuffs and finishing chemicals in the textile manufacturing sector. This standard scenario is structured in such way that it may serve as a prototype for other sectors as well. Once the drafting work is finished the outcome will be compared with VCI's categorisation approach in order to identify the main differences and/or similarities.

The current draft concept has been worked out by an ad-hoc working group consisting of 3 textile finishers, 3 companies manufacturing textile chemicals, the German Environmental Agency (UBA), 3 associations (representing textile manufacturers, textile finishers and producers of textile finishing chemicals) and a group of consultants. The standard-scenario and the exposure estimation tool is not yet ready however it may be useful to inform other working groups on the state of work carried out.

[2] Testing of selected elements of the REACH procedures in practise by authorities and companies in North Rhine-Westphalia (Germany); summary project report 22.12.03; www.europa.nrw.de;

3. Definition of relevant sub-scenarios

In a first step 3 relevant sub-scenarios were defined related to the emission pathways and the environmental compartments:

- Discharge of water-soluble substances to surface water (dilution scenario)
- Discharge of poorly water-soluble, organic substances to surface water including potential exposure of sediments, agricultural soil (via sewage sludge) and biota (via secondary poisoning) (accumulation scenario)
- Air emission related to textile finishing through foulard and printing processes

A waste scenario has not yet been drawn up.

4. Identification of factors driving the exposure

Based on the OECD Emission Scenario Document (ESD), the EU Technical Guidance Document on Risk Assessment for New and Existing Substances (TGD) and the practical experience of companies, five main factors have been defined: Each of the factors has been assigned to one of the actors in the chain having access to realistic, site or substance specific information. In order to allow for exposure estimate at the level of substance producer and formulator default values have been defined that can be overwritten with more realistic information whenever this becomes available.

- **Exposure relevant substance properties**: The substance producers usually determine the relevant substance properties, i.e. water solubility, vapour pressure, octanol-water partition coefficient (Log K_{ow}), biodegradation and the molecular weight. These parameters should be available and hence no defaults need to be defined.
- **Degree of fixation on the fabric**: There are two general cases, either the substance is made for fixation on fibre (e.g. dyes or optical brighteners) or it is a textile auxiliary remaining in the water e.g. like detergents (100% to wastewater). Although, many dyes and textile finishing chemicals fix to the fabric at a degree of more than 90%, a default of 70% is assumed in order to cover also textile finishing chemicals and residues from foulard dipping baths and printing processes.
- **Used amounts per time and frequency of use:** Usually the producer of a substance does not know the daily amount of a substance (contained in a textile finishing preparation) used at a certain site (local scenario). Also he does not know whether the substance is used continuously or only from time to time (e.g. not more than 1 day per month). Hence the producer will make a default assumption for his exposure estimate, e.g. 150 kg/day and daily use. Whether this is a realistic assumption for the maximum amount of a dye or a textile finishing substance has yet to be cross checked. In any case, the textile finisher can replace the default value by more realistic values
- **Elimination in biological wastewater treatment**: The biological elimination in a wastewater treatment plant depends on the biodegradability of the substance and the partitioning of the substance between sludge, air and water in the wastewater treatment plant. In the present type of assessment, results from the OECD standard screening biodegradation tests (OECD 301 and 302 B-C) and the *SimpleTreat* model (see TGD) are used to determine the elimination rates and the need to consider an air or sludge scenario.
- **Dilution in relevant environmental compartments:** Again the producer does not know about the relevant receiving water volume (wastewater and surface water) available to di-

lute the releases from wastewater treatment. Based on the TGD a default of 20.000 m^3/d is used, which again can be replaced by more realistic figures for the local situation.

The approach outlined above would also allow for setting up bands (categories) for substance amounts and dilution volume if this would further simplify the task for the actors in the supply chain.

5. Quantitative exposure assessment

Quantitative exposure calculation and comparison with the relevant Predicted No Effect Concentration (PNEC) is carried out by means of an excel spreadsheet. The spreadsheet contains a default value for each parameter and an option to overwrite the default value with more realistic information. If the following defaults for emission of a water soluble substance (biodegradability not demonstrated) via wastewater are used, a default PEC of 7.5 mg/l (100 % loss) results.

- Amount of substance used in a textile finishing company per day 150 kg (Draft ESD, 2003)
- Losses to wastewater 100 % (if substance is not intended to fix on the fabric) or 30% (reasonable worst case if substance is intended to fix to the fabric; based on industry information)
- Elimination factor for substance for which ready or inherent biodegradability is not demonstrated: 0%
- Volume of receiving local wastewater and river water: 20.000 m^3 /day

For many substances, this PEC is most likely significant higher than the PNEC and hence more realistic values need to replace the defaults if marketing and use shall be demonstrated to be safe. All three actors can contribute information available to them to screen out those conditions of use, for which in fact no further assessment is needed. For example, the daily amount is possibly not higher than 25 kg, the substance has turned out to be inherently degradable[3] and the available water volume for dilution is 2 million m^3/d instead of 20.000 m^3/d. In such case the PEC would be 7.5 µg/l (100 % loss). Any substance with an acute toxicity > 7.5 mg/l could be safely used even without further assessment of the degree of fixation to the fibre. However the manufacturer of the substance would need to state in his exposure scenario that safe use is only ensured if the daily amount does not exceed 25 kg and the receiving water volume is not below 2 million m^3 per day.

6. Refinement of information if PEC > PNEC

If this first cycle of safety assessment still leads to a concern (PEC > PNEC) the tool provides some guidance for a second safety assessment cycle with more specific and more realistic information. In many cases for example, a dye may fix to the fabric to a degree of 95% or the residues from the foulard dipping baths are minimised to 5% instead of 30%.

Only if this second round of safety assessment still ends with a concern, a further assessment on a case by case basis is needed.

[3] Based on the S*impleTreat model* the biological elimination of a water soluble, non-volatile organic substance in waste water treatment would be about 40% (see draft excel table). Accordingly, the discharge of losses to surface water is 60% instead of 100%.

7. Further Work

The wastewater scenario for water-soluble substances (> 1 mg/l and Log Kow < 3) in dye stuffs and textile finishing chemicals has been drafted so far. In the framework of the current project (final report in October) the following components of a standard exposure scenario will be added:

- Accumulation scenario via wastewater (soil, sediments and biota) for substances with a poor water-solubility but no PBT or vPvB properties.
- An element to calculate a regional PEC for substances with a total European market volume exceeding a certain threshold.
- Air emission scenario (based on the German „Bausteine-Concept“)[4]
- Interface to consumer exposure scenario
- Interface to the occupational exposure scenario

Once the draft standard-exposure scenario for the environment is completed, the result will be compared with the categorisation approach as proposed by the VCI. In this comparison, in particular the role of sectors specific emission and abatement factors will be discussed.

8. Concluding remarks

The results of the project will be fed into the scoping phase of REACH Implementation Project RIP 3.2 (Guidance on Preparing Chemical Safety Report) as well as into RIP 3.5 (Guidance on DU requirements). It is hoped that the outlined approach is workable and may help to screen out the majority of cases of “no concern” in a relatively simple way. For further information or comments please contact:

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[4] Instrument to predict specific substance loads and/or Corg loads (amount of organic substances in air measured as carbon content) from fabric finishing chemicals at temperatures between 120 °C to 220 °C in padding process.

DRAFT Environment exposure calculation for dye stuffs and textile finishing chemicals - Wastewater (Dilution Scenario)

	Trigger		Calculation	Producer/Importer				Formulator				Industrial User			
No.			Variable	value	enter	default	Dim	value	enter	default	Dim	value	enter	default	Dim
1a	**Biodegradability**	F_{min}		**0%**		0%	%	**0%**		0%	%	**0%**		0%	%
	inherently biodegradable		if yes: 40%	0%		nein	%								
	readily biodegradable ?		if yes: 70%	0%		nein	%								
	within 10 day window ?		if yes: 85%	0%		nein	%								
1b	**Adorption to sewage sludge**	F_{ads}		**0%**		0%	%	**0%**		0%	%	**0%**		0%	%
2	**Share not fixed to substrate**	F_{nfix}		**100%**		100%	%	**100%**		100%	%	**100%**		100%	%
	Fixation technically intended ?		if yes: 30%	100%		nein	%								
3	**Percentage in preparation**	C_{subst}						**100%**		100%	%	**100%**		100%	%
4	**Max. amount of substance used per day (site specific)**	Q_{subst}	C_{subst} x Q_{prep}	**150**		150	kg/d	**150**		150	kg/d	**150**		150	kg/d
	Max. amount of preparation used per day (site specific)	Q_{prep}													kd/d
5	**Receiving water volume**	Q_{water}	Q_{wwtp} + Q_{sw}	**20.000**		20.000	m3/d	**20.000**		20.000	m3/d	**20.000**		20.000	m3/d
	Volume of WWTP per day	Q_{wwtp}										2.000		2.000	m3/d
	Surface water flow per day	Q_{sw}										18.000		18.000	m3/d
	Resulting PEC		s. u.	**7500**			**µg/l**	**7500**			**µg/l**	**7500**			**µg/l**
	Comparison PNEC						**µg/l**				**µg/l**				**µg/l**
	intermittend release?		PNEC x 10												

Explanation:	= cells to enter data
bold	= parameters triggering the PEC

Formula for PEC-calculation:

$$\frac{Qsubst \times Fnfix \times (1 - Fmin) \times (1 - Fads)}{Qwater}$$