

elni-forum 1-2005
Environmental Law Network International
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Society for Institutional Analysis
 University of Applied Sciences, Darmstadt

**Implementation of risk reduction measures:
 Interface Problems between EC Chemicals Legislation
 and sector specific Environmental Legislation
 (IPPC/WFD)**

Martin Führ / Stefanie Merenyi
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**Core Question: Implementation of
 Risk Reduction Strategies (RRS)**

**How to implement substance related
 Risk Reduction Measures?**

- beyond Community wide marketing and use restrictions;
- to analyze for the Situation
 - under Existing Substances Regulation 793/93
 - under REACH
- and their conjunction with sector specific Environmental Legislation (IPPC/WFD)

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Overview

From “toxic ignorance” ...
... to cooperative risk reduction?

- I. Current legislative framework
- II. Risk assessment and risk reduction
(under 793/93/EEC and REACH)
- III. Example Toluene
- IV. Implementation of risk reduction measures
(Interfaces to sectoral legislation)
- V. Amendments: policy options

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I. Legislative Framework


Council Regulation EEC 793/93

on the **evaluation** and **control** of the risks of existing substances

Art. 1 (1) “This Regulation shall apply to:

- a) the collection, circulation and accessibility of information on existing substances;
- b) the evaluation of the risks of existing substances to man, including workers and consumers, and to the environment, in order to **ensure better management of those risks within the framework of Community provisions**”.

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I. Legislative Framework


- I. Art. 8 (1)


Commission, in consultation with Member States, shall regularly draw up ... **priority lists of substances** requiring immediate attention (CMRs)
- II. Art. 10 (1)

For each substance on the priority lists a **Member State** shall be given responsibility for its evaluation (fair burden sharing between Member States).
The Member State shall designate a **rappporteur** for that substance from among the **competent authorities**.
- III. Art. 9

For the substances included in the priority lists ... manufacturers and importers ... submit to the rapporteur ... **all relevant available information** and **corresponding study reports** for risk assessment of the substance concerned.
- IV. Art. 10

The **rappporteur** shall be **responsible for evaluating** the information submitted by the manufacturer(s) or importer(s) in conformity with ... **any** other available information.

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I. Legislative Framework

- v. Art. 10 (3)

The rapporteur for a given priority substance shall **evaluate** the risk of that substance to man and the environment.

Where appropriate, it shall suggest a **strategy for limiting these risks**, including control measures and/or surveillance programmes. Where such control measures include recommendations for **restrictions on the marketing or use** of the substance in question, the rapporteur shall submit an **analysis of the advantages and drawbacks** of the substance and of the availability of replacement substances.

The recommended **risk evaluation and strategy** shall be forwarded **to the Commission** by the rapporteur.

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II. Risk reduction measures under EEC 793/93

Focus on 3 examples

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Toluene

Navy Blue
(New substance)

Existing substances

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II. Substance Evaluation: 793/93

<p>Toluene</p> <p>Aniline</p> <p>-----</p> <p>(Navy Blue)</p>	}	<p>A. Risk Assessment Report (RAR)</p> <p>Exposure assessment (PEC)</p> <p>Effects assessment (PNEC)</p> <p>Risk characterisation:</p>	} Environment (Human Health: DNEL)	} PEC/PNEC > 1
<p>criteria:</p> <ul style="list-style-type: none"> - effectiveness - practicality - economic impact - monitorability 	}	<p>→ i, ii, iii (iv)</p> <p>B. Risk Reduction Strategy (RRS)</p>		
		<p>C. Risk Reduction Implementation (RRI)</p>		

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
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Existing Chemicals							
HOME	DOCUMENTS	I DATA COLLECTION	II PRIORITY SETTING	III RISK ASSESSMENT	EUSES	HEDSET	IUCLID
Existing Substances Regulation-Results							
<p>Substances on priority lists must undergo an in-depth Risk Assessment, following the framework set out in Commission Regulation (EC) 1488/94 and implemented in the detailed TGD on Risk Assessment for New and Existing Substances.</p> <p>The drafts of the Risk Assessment Reports (RARs) are written by the Member States which act as "Rapporteurs". The Commission mediates the Technical Meetings that are aimed to reach consensus on the conclusions of the RAR. The draft RARs in this table are agreed by the Technical Meeting and have been submitted to the CSTEE for their opinion.</p> <p>The comprehensive reports (column "Final RAR") and summaries (column "Summary") are published on this website after adoption by the Member States, taking into account the opinion of the CSTEE. A summary of the conclusions of the Risk Assessment and the proposed risk reduction strategy is published in the Official Journal as a Commission Recommendation (column "OJ Recommn.").</p> <p>The volumes from 1 to 9 regarding the substances alkanes, c10-13, chloro, diphenyl ether, pentabromo deriv., cumene, acrylaldehyde hydrogen fluoride, 4,4'-methylenedianiline are also available as hard copies and can be ordered to the Publications Office in Luxembourg or through the sales agents worldwide.</p>							
CAS#	EINECS#	Substance Name	Draft RAR	Summary	Final RAR	OJ Recomm.	
60-00-4	200-449-4	EDETIC ACID	>view	-	-	-	
62-53-3	200-539-3	ANILINE	>view	-	-	-	RRS
64-02-8	200-573-9	TETRASODIUM ETHYLENEDIAMI	>view	-	-	-	RRI
		METHACRYLAMIDE	>view	-	-	-	
		CHLOROFORM	-	-	-	-	
67-66-3	200-663-8	PROPAN-1-OL	>view	-	-	-	
71-23-8	200-746-9	BENZENE	>view	-	-	-	
71-43-2	200-753-7	ACETONITRILE	>view	>view	>view	-	
75-05-8	200-835-2	CHLORODIFLUOROMETHANE	>view	>view	>view	-	
75-45-6	200-871-9	METHYLOXIRANE	>view	>view	>view	-	
75-56-9	200-879-2	TERT-BUTYL HYDROPEROXIDE	>view	-	-	-	
75-91-2	200-915-7	HEXACHLOROCYCLOPENTADIENE	>view	-	-	-	
77-47-4	201-029-3	DIMETHYL SULPHATE	>view	>view	>view	-	>view
77-78-1	201-058-1	TRICHLOROETHYLENE	>view	>view	>view	-	>view
79-01-6	201-167-4	ACRYLAMIDE	>view	>view	>view	-	
79-06-1	201-173-7	ACRYLIC ACID	>view	>view	>view	-	
79-10-7	201-177-9	CHLOROACETIC ACID	>view	>view	>view	-	
79-11-8	201-178-4	METHYL ACETATE	>view	>view	>view	-	
79-20-9	201-185-2	METHACRYLIC ACID	>view	>view	>view	-	
79-41-4	201-204-4	2,2',6,6'-TETRABROMO-4,4'-ISOPROPYLIDENEDIPHENOL	>view	>view	>view	-	
79-94-7	201-236-9	4,4'-ISOPROPYLIDENEDIPHENOL	>view	>view	>view	-	
80-05-7	201-245-8	METHYL METHACRYLATE	>view	>view	>view	-	
80-62-6	201-297-1	4'-TERT-BUTYL-2',6'-DIMETHYL-3',5'-DINITROACETOPHE	>view	-	-	-	
81-14-1	201-328-9	NONE	>view	-	-	-	
		5-TERT-BUTYL-2,4,6-TRINITRO-M-XYLENE	>view	-	-	-	


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II. Risk reduction measures: 793/93

- Since 1994: 4 priority lists (latest: October 25 th, 2000) with a total of 141 substances
- Some 70 substances have undergone the evaluation procedure so far (<http://ecb.jrc.it/esis/> June 29th, 2005)
 - Risk Assessment Report
 - 76 Drafts RAR
 - 56 (for 59 substances) Summaries
 - 52 (for 55 substances) Final Reports
 - 3 Addendums
 - 83 Conclusions
 - 31 Risk Reduction Stragies
 - 28 COM-Recommendations (O.J.)
- Implementation of the Recommendations ???


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Aniline Toluene


III. Example


RISK ASSESSMENT

Toluene

CAS-No.: 108-88-3
EINECS-No.: 203-625-9

Final Report - Marts 2001





Danish Environmental Protection Agency

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View of the policy
Programme 2003-2008
Health Information
Threats to health
Health determinants
Enlargement
International cooperation

Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE)

assessment > Scientific committees > On Toxicity, Ecotoxicity and the Environment > Opinions

Opinion on the results of the Risk Assessment of: TOLUENE - Human health and Environment - CAS No.: 108-88-3 - EINECS No.: 203-625-9 - Report version : Final report - March 2001 carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances¹. Opinion expressed at the 24th CSTEE plenary meeting, Brussels, 12 June 2001

Terms of reference

In the context of Regulation 793/93 (Existing Substances Regulation), and on the basis of the examination of the Risk Assessment Report the CSTEE is invited to examine the following issues:

- Does the CSTEE agree with the conclusions of the Risk Assessment Report?
- If the CSTEE disagrees with such conclusions, the CSTEE is invited to elaborate on the reasons for this divergence of opinion.


GENERAL COMMENTS

Toluene is a high production volume (HPV) substance. In 1995, the estimated EU consumption was 2800 Ktonnes, including a production of 2600 Ktonnes. Once isolated from refinery streams of crude oil, it is used in a large number of industrial branches and consumer products such as in closed system to manufacture other chemicals and as a solvent carrier in paints, thinners, adhesives, inks and pharmaceuticals products and as an additive in cosmetic preparations. In addition, toluene is also released naturally e.g. by volcanoes and forest fires.

Once emitted to the air, toluene combines with oxygen to form benzaldehyde and cresol. In addition, it contributes to the tropospheric formation of ozone. Some of these degradation and reaction products have been identified by the authors of the RAR but they have not been evaluated. It is the CSTEE opinion that they should be assessed. Last but not least, as also mentioned in the RAR, the production and use of gasoline (120,000 Ktonnes containing approximately 14,000 Ktonnes of toluene) has not been included in the present risk assessment of toluene. Given that the effects of toluene on humans and the environment are the same whatever its origin, the choice not to take into account the presence of toluene in gasoline makes the assessment of limited relevance to the actual impact of toluene on both the environment and the human health. Furthermore in one exposure scenario for consumers, filling gasoline at self-service gas station is considered. This is contradictory to the above mentioned statement to not consider toluene in gasoline, in addition, in this context, exposure of workers should be considered as well.

Related to Risk Assessment

- ✓ Speeches
- ✓ Press Release
- ✓ Events
- ✓ Publications
- ✓ Links
- ✓ Key documents
- ✓ Legal documents
- Projects

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HBS-Projektbeirat

14.03.2003 - 6

Date of Last Literature Search: 2000
 Review of report by Member State
 Technical Experts finalised: 2000
 Final report: 2003

European Chemicals Bureau
 Institute for Health and Consumer Protection
 European Union Risk Assessment Report
 CAS No: 108-88-3 EINECS No: 203-625-9
 Existing Substances
 toluene
 CH₃
 2nd Priority List
 Volume: 30
 EUROPEAN COMMISSION
 JOINT RESEARCH CENTRE
 EUR 20539 EN

III. Example Toluene

1. Risk Assessment Report (RAR)

Evaluation: Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE; since 2004: SCHER)

- „With the exception of the above remarks, both parts (environment and human health) of the RAR are of
- good quality and the CSTEE
- generally agrees with the conclusions.“

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Toluene

III. Example Toluene

1. Risk Assessment Report (RAR)

CSTEE-Evaluation

Environment: Exposure assessment

- Toluene is emitted in large quantities.
- Because it is a volatile organic compound emission is mostly to the air compartment,
- however water contamination is also possible through discharges from industrial sources.
- Toluene binds loosely to soil and therefore through leakage, may enter groundwater.

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
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III. Example Toluene

1. Risk Assessment Report (RAR)

Total emission	<i>Continental</i>	<i>Regional</i>
– to air	1090 t/day	122 t/day
– to waste water	180 t/day	20 t/day
– to surface water	77 t/day	8.6 t/day
– to industrial soil	2.4 t/day	0.3 t/day

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III. Example Toluene


1. Risk Assessment Report (RAR)

CSTEE-Evaluation

Environment: Risk characterisation

- A very detailed study of the various PEC/PNEC ratio for the different compartments has been conducted in the report and the conclusions are sound.
- Even if, due to degradation and volatility, the half-life of toluene in the aquatic environment is relatively low, the high level of emissions may produce relatively high concentrations at local level. Therefore, PEC/PNEC values higher than 1 can be calculated in various site-specific conditions.
- The risk characterisation combines generic and specific assessments when the information is available. The conclusions are considered scientifically sound.
- The CSTEE agrees with conclusion iii (need for limiting the risk) applied to some site-specific production, processing and downstream use conditions.


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III. Example Toluene


2. Risk Reduction Strategy

RRS-Structure

1. Background
2. The risk assessment (RAR-findings)
3. Current risk reduction measures
4. Potential risk reduction measures
5. Assessment of possible further risk reduction measures
6. Risk reduction recommendations
7. Marketing and use restrictions
8. Possible monitoring arrangements

criteria:

- effectiveness
- practicality
- economic impact
- monitorability


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III. Example Toluene

2. Risk Reduction Strategy

Conclusion of the environmental risk assessment (Danish EPA, 2001)

Life Cycle Stage	Industry Sector	Risk to surface water	Risk to STP	Risk to soil
Production	2 sites (out of 19)	iii	ii	ii
	All other	ii	ii	ii
Production and Processing	1 site (out of 7)	iii	ii	ii
	All other	ii	ii	ii
Processing	1 site (out of 6 incl. in the main manufacturer study)	ii	ii	iii
	1 site (out of 6 incl. in the main manufacturer study)	iii	iii	ii
	All other	ii	ii	ii
Down-stream uses	Industry (use as intermediate)	iii	iii	iii
	Industry (use as solvent)	iii	iii	iii
	Mineral oil and fuel (use as solvent)	iii	ii	iii
	Polymers (use as process regulator)	iii	ii	iii
	Paint, etc. (use as solvent)	iii	ii	iii
	Industry (use as extraction agent)	iii	iii	iii
	Personal/domestic (use as solvent)	ii	ii	ii
	Pulp, paper and board (use as solvent)	ii	ii	ii
	Textile (use as solvent)	iii	ii	iii
	Other (other uses)	ii	ii	ii

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
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III. Example Toluene

3. COM-Recommendation

O.J. 2004, No. L 144/117 (study, p. 31)

- Environment/Humans via Environment:
 - a) Water discharges
 - b) Industrial installations (IPPC)
 - c) Control of local emissions

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III. Example Toluene


3. COM-Recommendation

a) water discharges

„It is recommended,

- that (...) the European Commission should consider the inclusion of toluene in the priority list of Annex X to WFD during the next review of this Annex
- but that, in the meantime, toluene should be considered as a relevant List II substance in Council Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community,
 - thus requiring the establishment of national
 - quality objectives,
 - monitoring and
 - eventual reduction measures,
 - as to ensure that concentrations in surface water systems do not exceed the quality objective.”

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
III. Example Toluene

3. COM-Recommendation

b) industrial installations

- to facilitate permitting under IPPC that this substance is included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).
- It is recommended that Member States should carefully monitor the implementation of BAT by permitting and
- report any important developments to the Commission in the framework of the exchange of information on BAT.

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III. Example Toluene


3. COM-Recommendation

local emissions

... to the environment

- should, where necessary, be controlled
- by national rules
- to ensure that no risk for the environment is expected.


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IV. Addressing the Interface problem


Chemicals legislation ↔ sectoral legislation

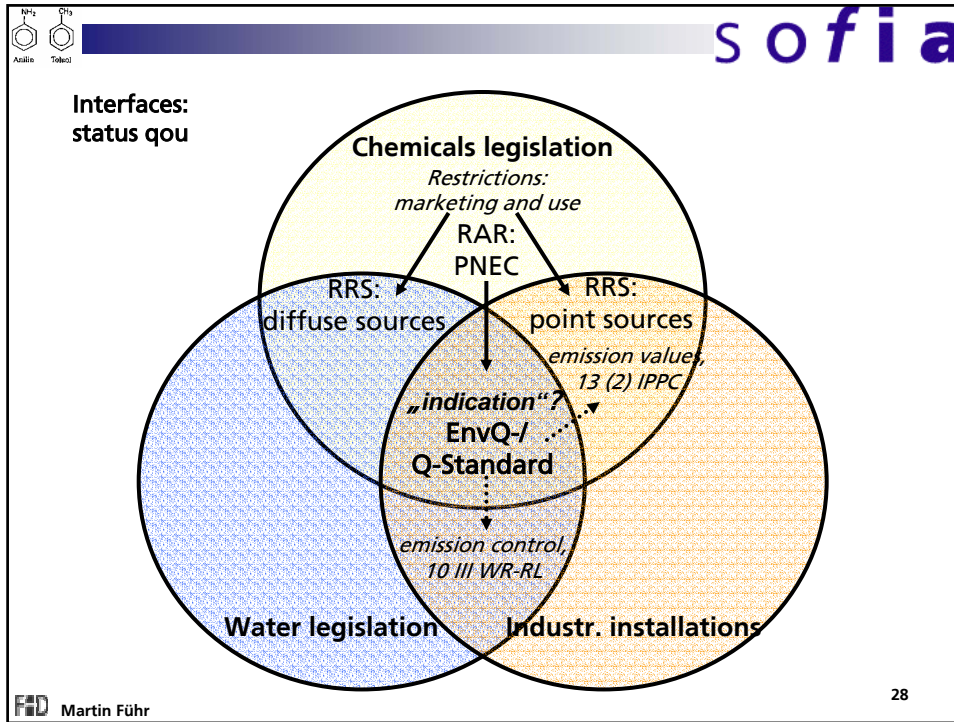
Legal starting points

1. Immission related: PNEC/DNEL → (Env.) Quality Standard
 - Art. 10 (3) WFD (*by way of interpretation*)
2. Art. 10 (3): Where a quality objective or **quality standard**, whether established pursuant to this Directive, in the Directives listed in Annex IX, or **pursuant to any other Community legislation**, requires **stricter conditions** than those which would result from the application of paragraph 2, **more stringent emission controls** shall be set accordingly. environmental quality standards.

Art. 13 (2): The reconsideration shall be undertaken in any event where:

- the **pollution** caused by the installation is of **such significance** that the existing **emission limit values** of the permit need to be **revised** or new such values need to be included in the permit


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V. Regulatory options

0. Initial Considerations


- strict connection → Burden to the RAR/RRS-procedure
- loose connection → Absence of Implementation

Modells:

- (1) Comprehensive substance flow control (Rehbinder, Enquete Comm. u.a.)
- (2) „Side by side“, additive (status qou)
- (3) „Side by side“, cooperative (proposed solution) using the **specific capacity**:
 - chemicals law:
 - generating information on substance properties
 - REACh: Initiate cooperation of actors along the value chain?
 - sectoral law: using their specific scope of application


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
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V. Establishing specific links


- 1. EC-level**
 - Regulation/Directive
 - Amendment of IPPC/WFD: Establish specific links explicitly
 - General provision: PNEC/DNEL as minimum “(environmental) quality standard”,
 - e.g. Art. 10 (3) WFD/Art. 10 IPPC
 - Inclusion in REACH-Process?
 - PNEC/DNEL accessible in REACH database (Art. 73 (2) d REACH); incl. information on the background of the data
 - Transition clause for Existing Substances Regulation mechanisms
 - Guidance Documents
 - TGD-Risk Reduction Implementation (Assistance: Priority setting; „translation“)
 - Incorporation in BREFs

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V. Establishing specific links

- 2. National level**
 - Legal assumptions (PNEC = quality standard)
 - Regulative level (waste water regulation)
 - Implementation guidelines (Technical Instruction on air quality)

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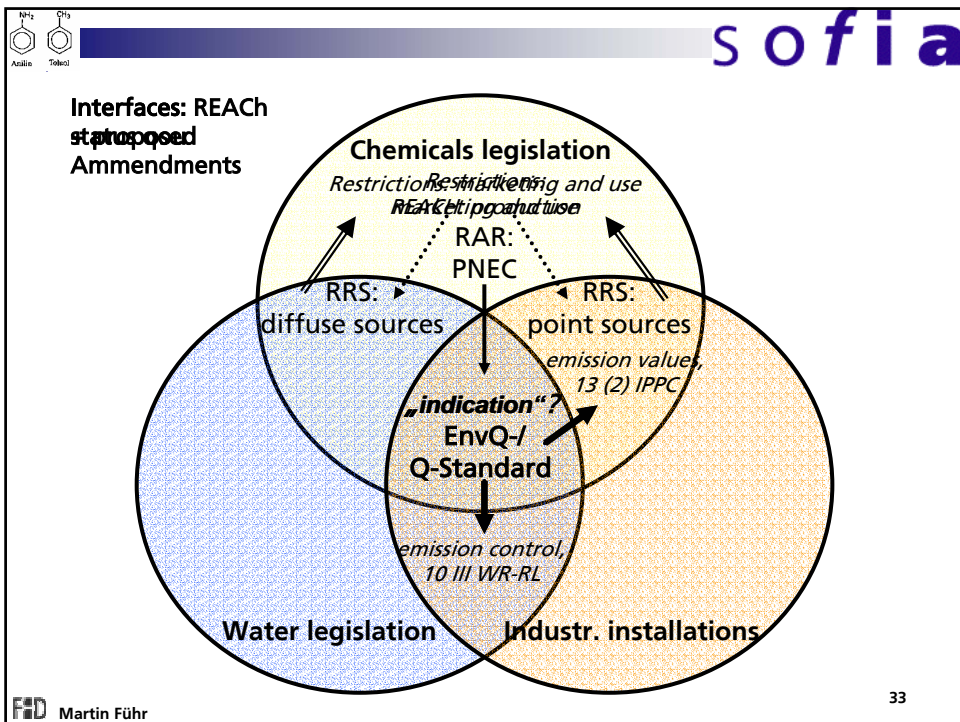
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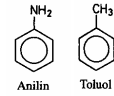
V. Establishing specific links

3. Monitoring

- General transparency provisions:
 - EPER/PRTR
 - model TRI?
- Installation-/media-specific provisions
 - WFD
 - IPPC

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University of Applied Sciences, Darmstadt

Thank You for Your Attention

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Enquete Commission of the German Bundestag on the "Protection of Humanity and the Environment" (ed.)

Responsibility for the Future
Options for Sustainable Management of Substance Chains and Material Flows

F&D Martin Führt **Economica Verlag**

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
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Selected literature on materials flows institutional framework

- Enquete Commission of the German Bundestag on the „Protection of Humanity and the Environment“ (ed.): Responsibility for the Future – Options for Sustainable Management of Substance Chains and Material Flows, Bonn 1994 (Economica).
- Führ et al.: Institutionelle Bedingungen zur Förderung proaktiver Strategien - Vergleichende Analyse internationaler Ansätze im Bereich des Umweltverhaltens von Unternehmen, Führ, M. unter Mitarbeit von Bizer, K./Gebers, B./Roller, G., in: Enquête-Kommission "Schutz des Menschen und der Umwelt" (Hrsg.), Umweltverträgliches Stoffstrommanagement, Bd. 2: Instrumente, Bonn 1995 (Neudruck: Sofia-Studien zur Institutionenanalyse Nr. 99-1).
- Frieger/Engelhardt/Henseling (Hrsg.): Das Management von Stoffströmen, Berlin 1998 (Springer).


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
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Selected literature on the behavior model (homo oeconomicus institutionalis + responsive regulation)

- Simon, Herbert A. 1957: Models of Man, New York.
- Nonet, Phillippe/Selznick, Philip 1978: Law and Society in Transition - Towards Responsive Law, New York (Harper & Row).
- North, Douglass C. 1990: Institutions, Institutional Change und Economic Performance, Cambridge (University).
- Kirchgässner, Gebhard 1991: Homo oeconomicus, Tübingen (Mohr).
- Bizer, Kilian 1998: Individuelles Verhalten, Institutionen und responsives Recht (Sofia-Diskussionsbeiträge zur Institutionenanalyse 98-3), Darmstadt.
- Bizer, K./Führ, M./Hüttig, C. (Hrsg.) 2002: Responsive Regulierung - Beiträge zur interdisziplinären Institutionenanalyse und Gesetzesfolgenabschätzung, Tübingen (Mohr-Siebeck).
- Führ, M. 2003: Eigen-Verantwortung im Rechtsstaat, Berlin (Duncker & Humblot).


Discussion-papers: www.sofia-darmstadt.de
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
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