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Interface Problems between EC Chemicals Law and sector-specific Environmental Legislation (IPPC/WFD)

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Key to abbreviations

Fig.	Figure
OJ	Official Journal of the European Union
RAIP	Rehabilitation of abandoned installations program
BAT	Best available technology
BREF	Best available technology reference document
COD	Chemical oxygen demand
CSA	Chemical safety assessment
CSR	Chemical safety report
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
ED	Environment Daily (information service)
EC	European Community/European Community treaty
EINECS	European Inventory of Existing Commercial Substances
ELINCS	European List of Notified Chemical Substances
ELV	Emissions limit value
EPER	European Pollutant Emission Register (www.eper.de/)
EQS	Emissions Quality Standard
EU	European Union
EEC	European Economic Community
DSD	Dangerous Substances Directive
HPVC	High Production Volume Chemicals Existing Chemicals which, pursuant to Article 3 of the Existing Substances Regulation (ESR), are manufactured or marketed in quantities exceeding 1000 t/y
IPPC	Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control
LOAEC	Lowest Observed Adverse Effect Concentration
LVOC	Large Volume Organic Chemical
NOAEL	No Observed Adverse Effect Level
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
PRTR	Pollutant Release and Transfer Register
RAR	Risk Assessment Report
REACH	Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Volume 1, cited as REACH; or as REACH plus Annex no.)
RRS	Risk Reduction Strategy
TGD	Technical Guidance Document
UN-ECE	United Nations Economic Commission for Europe
VOC	Volatile Organic Compound

WFD Water Framework
Directive (2000/60/EC)

Key to applicable risk phrases

R 11	Highly inflammable
R 20	Harmful by inhalation
R 40	Limited evidence of a carcinogenic effect
R 43	May cause sensitization by skin contact
R 50	Very toxic to aquatic organisms
R 53	May cause long-term adverse effects in the aquatic environment
R 60	May impair fertility
R 61	May cause harm to the unborn child
R 63	Possible risk of harm to the unborn child
R 68	Possible risk of irreversible effects
R 48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation

Official wording pursuant to Annex 3 of the 28th adaptation of Directive 67/548/EEC to technical progress, OJ L 225, p. 85 et seq. of August 21, 2001.

A

Scope of the study

Toxic ignorance has become a major issue in the current debate on chemicals policy both in the EU and the US.[1] The term refers to a lack of knowledge of the health and environmental properties, as well as the mechanisms of action, of Existing Chemicals. There can be little doubt that this term also goes to the heart of the problem facing us today. However, the availability of such data – at any rate for individual substances – gives rise to a new problem, which is that such data must now be evaluated in light of the actions that need to be taken.

Efforts are now being made to reach this second phase for the more than 70 chemicals that are subject to the EU's Existing Chemicals regime. For some of these substances there currently exists both a Risk Assessment Report (RAR) as well as EU-promulgated Risk Reduction Strategies. Now that the toxicological properties of these substances have been successfully described, we face two tasks: (a) we must implement what are regarded as minimum measures and (b) we must leverage the detoxification potential that has been identified. And we must do this in light of the impact these chemicals have on human health and the environment. The present study focuses on environmental impact. However, most of our findings – particularly in regard to the effects of chemical impact thresholds on compliance with other regulations[2] – are also applicable to the health effects of the substances under consideration here.

The Federal Environmental Agency's invitation to bid that gave rise to the present study posits that the EU presently lacks the instruments needed to achieve compliance with the aforementioned thresholds (the so-called *instrument gap*). Against this backdrop, the present study sets out to determine whether the EU currently has at its disposal the legal and administrative instruments that are needed in order to implement the Community's risk reduction strategies

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[1] Environmental Defense Fund 1997; Massachusetts Precautionary Principle Project 2000; Winter 2000a; v. Holleben 2002; Rehbinder 2003, Rn. 29 ff. and 214 ff.

[2] See the following recommendations: E1, p. 56 and H2, p. 99.

for Existing Chemicals. (For a summary of the study's findings and conclusions see section H, pp. 100).

B

Study methodology; approach to the problem

The study took as its starting point current EU Existing Chemicals regulations, whose primary purpose is to enable restrictions on the use and marketing of chemical substances. However, current EU chemicals regulations do not allow for restrictions on other chemical-induced risks such as those engendered by the manufacture and processing of chemicals. However, this does not mean that the EU is powerless to enforce Community regulations in this realm. These powers are assured by Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention in conjunction with air quality standards, as well as the Water Framework Directive and other instruments. In addition to these directives, the EU also has at its disposal specific substance and substance-group regulations, e.g. for volatile organic compounds (VOC directive).

However, we need to gain greater insight into the *regulatory interfaces* between EU chemicals regulations and other sectoral regulations whose application domains fall within the purview of reduction measures whose implementation is not governed by EU chemicals regulations.

Where *regulatory interface problems* come to light in the course of the present analysis, the question arises as to whether such problems can be resolved or at least mitigated by means of *institutional innovations*.[3] This could potentially be realized by modifying these regulatory interfaces within the framework of EU legislation, which in most cases would mean changing existing EU laws and the attendant Member State implementation procedures. If on the other hand, it emerges that current regulatory interfaces are appropriately structured, another solution might be to define more precisely the administrative "transfer" mechanisms between the various environmental regulation domains.

[3] For a discussion of interdisplinary institutional analysis, see B3, p. 6.

1

The underpinnings and aims of EU law

When jurists are asked how the EU should go about reducing substance-related environmental risk throughout the Community and which instruments should be used to do this, they assign their question to general legal categories that take their cue from the legal principles set forth in the EU and EC treaties. From these categories, assessment criteria can be extrapolated that allow to evaluate the findings of the present study.

One of the missions of Community institutions that is anchored in primary law is to strive for "a high level of protection and improvement of the quality of the environment" (Article 2 EC). This objective is reiterated in Article 174 of the Treaty, which obligates the Community to achieve a "high level of protection." This means that the Community must not only pass environmental regulations but must also practice environmental stewardship in regulating the internal market (Article 95, par. 3 EC). The proposed REACH law is an instance of a regulation that seeks to accomplish this aim.

The integration clause of Article 6 EC "Environmental Protection Requirements" requires even greater involvement on the part of all political stakeholders in the Community, particularly when it comes to "promoting sustainable development."[4] Significantly, the integration clause expressly states that Community policies must be stipulated *and implemented*, which means that regulations must not only be promulgated but also actively applied. Thus, it is not enough for the EU to merely enact regulations that look good on paper but are in reality paper tigers lacking the mechanisms that could translate into an acceptable impact level (including in conjunction with various other instruments and their implementation by the Member States).

[4] See the eighth recital of the EU Treaty, which states as follows:
"Determined to promote economic and social progress for their peoples, taking into account the principle of sustainable development and within the context of the accomplishment of the internal market and of reinforced cohesion and environmental protection, and to implement policies ensuring that advances in economic integration are accompanied by parallel progress in other fields."
(pertains to the principle of sustainability mentioned in Article 2, indent 1, EU Treaty)

In other words, the instruments should have an impact on *stakeholders' actions* vis-à-vis primary law.

The environmental policy goals and principles stipulated by the EC Treaty apply to all policy areas for which the Community has exclusive competence, and particularly to regulations governing materials and products that are marketed within the Community.[5]

The EC Treaty also obligates the Community to adhere to specific principles. For instance, Article 174 par. 3 EC stipulates that Community policy on the environment is to be based on "the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."

These tenets of primary law determine the manner in which Community regulations are construed and applied, as well as their long-term evolution. Thus, the answer to the question as to which regulatory or administrative innovations could remedy the lack of implementation instruments for risk reduction strategies is this: the principles laid down by the EC Treaty should constitute the gold standard when it comes to evaluating recommendations in this realm. Moreover, the scope of the present study would be too narrow if it limited itself to the legal aspects of the problem at hand. Thus, in the interest of carrying out its mission fully and appropriately, the study also makes recommendations pertaining to the optimization of environmental quality.

A second level of criteria which, in conjunction with the principle of proportionality,[6] can be regarded as the embodiment of the aforementioned tenets of primary law, is found in the application of the principles of secondary law pursuant to the Commission's technical guidance document (TGD) on Existing Chemicals.[7] According to this TGD, the EU's risk reduction strategies should fulfill the following criteria: effectiveness, practicality, economic impact, and

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[5] See the third REACH recital (REACH, 60).

[6] This (along with the attendant core criterion of necessity) is embedded in Article 5 paragraph 2 EC Treaty. It counts as a basic legal principle as well as one of the unwritten underpinnings of Community law (see Court of Justice of the European Communities, Rs. C-161/96 – Südzucker – Slg. 1998, I-281).

[7] See E, p. 56.

monitorability. If reduction measures are defined on the basis of these criteria and it emerges that existing EU implementation instruments are unable to realize measures that fulfill these criteria, an “instrument gap” can be said to exist (at least from an EU perspective) and the question then arises as to whether and how this gap can be overcome – if necessary in cooperation with the Member States.

2

Instrument gaps and implementation deficits

The instrument gap phenomenon is no stranger to the realm of environmental law. Indeed, under the guise of “implementation deficit”, instrument gaps have been widely discussed in environmental law and policy circles over the past several decades (Mayntz 1978). The term “implementation deficit” implies that the problem lies in the failure to implement administratively the provisions of regulations that are currently in force. The discrepancy between targeted aims and results achieved that is connoted by the term is perceived as a performance shortfall on the part of government authorities.

However, this view overlooks the fact that a multidimensional problem is involved here, and that a piece of legislation lies at the heart of every implementation deficit. If lawmakers devise elaborate and complex regulations but fail to provide government authorities with the tools they need to implement these regulations, a “first order” implementation deficit can be said to exist at the legislative level (Führ 1989, page 8 and 240) – or, put another way, an “instrument gap.”

However, a clear distinction needs to be made between a full-fledged instrument gap and a second-order implementation deficit. In the latter case, lawmakers have provided suitable implementation instruments, but government authorities are unable to apply them widely enough. This discrepancy between targeted aims and results achieved is generally not (solely) the fault of the implementing authorities, but is in most cases attributable to the fact that the incentive structure to which both government employees and societal stakeholders are subject is constituted in such a way that legal regulations are unlikely to be fully implemented. In other words, the abstract presence of the competence of a given governmental authority (e.g. the subsequent orders stipulated by Article 17 of the German Federal Immission Control Act (BIMSchG) or

the permit restrictions stipulated in section 5 of the German Water Resources Management Act (WHG)) are insufficient when the institutional context and attendant incentive structure fail to motivate stakeholders to take action that will lead to implementation of the regulation in question.

Finally, there are third-order implementation deficits, which occur intra-organizationally and pertain to the regulations governing (among other things) the ways organizations obtain and disseminate information, including within the context of EU laws such as REACH (see section F). Although regulations in such scenarios do lay down specific guidelines governing organizational behaviour, in the case of a third-order implementation deficit it proves impossible to integrate such regulations completely (or at all) into organizational or trans-organizational processes. The EU has instituted a support system known as the Eco-Management and Audit Scheme (EMAS) whose regulatory framework can be used by organizations as a basis for their environmental management systems.

Thus, this study focuses on the issue of “instrument gaps,” which are themselves rooted in first-order implementation deficits. However, insofar as evaluation of the relevance of a given regulatory interface problem and the attendant remedies comes into play, second-order implementation deficits must also be taken into consideration, for it is only in this way that the regulatory and practical requirements pertaining to chemical policy stipulated by Articles 2, 6, and 174 EC can be met. Against this backdrop, the significance of third-order implementation deficits is determined by whether it appears certain that REACH risk reduction strategies can be implemented.

3

The interplay between the legal and behavioural dimensions of institutional analysis

The observations made thus far have specific methodological ramifications for the present study. Whereas the classic legal perspective tends to focus on governmental authority competence and the attendant preconditions for government intervention with a view to defining terms precisely and achieving systematic consistency, in order to make sense of a second- and third-order implementation deficit, we must also investigate those drivers of institutional behaviour that lie outside the semantic and statutory realms. Thus,

consideration must also be given to institutional factors that require stakeholders to modify their behaviour so as to implement risk reduction strategies. This extended analytic framework forms the basis for a research paradigm known as interdisciplinary institutional analysis (Bizer 1998 and 2002, Führ 2003).

Applying this paradigm to determining whether EU substance regulations suffer from an instrument gap raises the question as to which incentive structures are generated by a scenario in which the emissions behaviour of identified point sources (e.g. for IPPC-based rehabilitation of abandoned installations programs) has to be modified in such a way as to comply with specific reduction targets. In this context, consideration must also be given to the dynamics of the relationship between, on one hand, operators' motivations and vested interests, and, on the other, regional installation monitoring and water resources authorities, including the competent government authorities, whose job it is to oversee the behaviour of these industrial stakeholders. Another factor that should be weighed in the balance here is the extent to which monitoring mechanisms could contribute to the implementation of EU-wide reduction strategies for Existing Chemicals, since this could also engender productive motivational impulses.

Only through the interplay of these structures – strengthened, where appropriate, by a monitoring system that serves to identify "new problems with existing substances" – can we hope to realize the goal stipulated by Article 2 EC Treaty of achieving "a high level of protection and improvement of the quality of the environment."

4

Structure of the study

This report describes the current EU Existing Chemicals assessment procedure and the attendant risk reduction strategies (section C) and, using three substances as case studies (section D),[8] discusses ways in which the requisite risk reduction measures can be implemented (section E). To date, the key actors in the realm of chemicals laws (and thus the focus of the current study) have been government

[8] The examples are based solely on data that was available as at July 2004, and no subsequent data has been used.

authorities, whether in the guise of Community institutions (including organs in charge of implementing the Existing Substances Regulation) or the application by government authorities of Member States of sector-specific EU regulations as implemented by national laws.

In addition to the Existing Substances Regulation, the present study also analyzes the problem of the interface between REACH and other sector-specific regulations. In the final section of the report, these findings are applied to the restructuring of EU chemicals regulations, i.e. the REACH Regulation and the instruments defined therein.

Under the REACH Regulation, the regulatory interface problem takes on a different cast because REACH shifts the moorings of Existing Substances risk reduction from the realm of legislative and administrative policy and strategy to a far greater emphasis on economic stakeholders taking responsibility for their own actions. This will also mean that private sector stakeholders will have more latitude to take action on their own.[9]

However, before this shift actually takes place, the question arises as to whether an interim strategy should be elaborated that would enable a transition from the current regulatory framework to REACH (section G) so as to ensure that Community level risk reduction strategies do not get lost in the legislative shuffle of multifarious monitoring models.

The report concludes (section H) with a recapitulation of the regulatory interface problem and possible solutions to it.

In order to ensure that the discussion of the issues in this report are as updated as possible, two technical issues pertaining to the study's research methodology had to be dealt with. This was done within the framework of two meetings that were held at the Federal Environmental Agency one (a closed-door session) on 1 June 2004, and a second session, an open meeting on Aug. 26, 2004 at which the analyses and proposals contained in a preliminary version of this report were discussed. We would like to take this

[9] The implications of this development for successful risk reduction are the subject of a study that was commissioned by the German Ministry of the Environment (FKZ 204 67 462/04).

opportunity to thank all those who attended these meetings. The results of these discussions have been incorporated into the report.

C

Stipulations of the current EU Existing Substances Regulation

1

Elaboration and adoption of a risk reduction strategy

The current EU Existing Substances Regulation is primarily based on Council Regulation no. 793/93[10] "on the evaluation and control of the risks of existing substances."

a)

Aims and scope of the Existing Substances Regulation

Although the Regulation juxtaposes the terms "evaluation" and "control" as if they carried equal weight, the provisions of the Regulation mainly focus on evaluation. Article 1 of the Regulation defines its aims and scope as follows:[11]

> 1. This Regulation shall apply to:
>
> (a) the collection, marketing 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.***

Thus the aims of the Regulation in terms of risk reduction for Existing Substances are defined in a startlingly vague manner ("better management"). Accordingly, the recitals mainly focus on risk analysis and – in keeping with the tradition of toxic ignorance – gathering the information needed for this process. Recital 13 confines itself to the following statement on the subject of risk reduction:

> The results of the risk evaluation of the priority substances, and the recommended strategy shall be adopted at Community level (...)

---

[10] Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, OJ L no. L 84, 5. 4. 1993, 1. See also Rehbinder 2003, Rn. 81 ff.

[11] In the present section of the report, all instances of "Article" without a specific document designation refer to the Existing Substances Regulation.

Nonetheless, a risk evaluation strategy is expressly mentioned here.

b)
Risk evaluation and risk reduction strategies

Article 10 paragraph 3 of the Existing Substances Regulation stipulates the following in regard to risk evaluation and risk reduction strategies:

> 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.

Risks are evaluated on the basis of Regulation No 1488/94/EEC[12] pursuant, in principle, to the criteria complementary set for the new substances listed in Commission Directive 93/67/EEC[13]. Article 3 paragraph 4 of this Directive stipulates that the risk assessment must reach one (or more) of four possible conclusions, the last and most far reaching of which states as follows: “The substance is of concern and the competent authority shall immediately make recommendations for risk reduction.” The procedure for this “environmental concern” test is laid down in Annex III of the Directive, of which an excerpt is provided in the box below (the text is essentially the same as the Annex of Directive 93/67[14]).

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[12] Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93.

[13] Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC.

[14] The structure of the risk characterization process will remain essentially unchanged under REACH. See REACH Annex 1 No 3-6 for information regarding substance assessment and the preparation of Chemical Safety Reports.

Commission Regulation (EC) No 1488/94
ANNEX III RISK ASSESSMENT: ENVIRONMENT (extract)

1. HAZARD IDENTIFICATION

The objective shall be to identify the effect(s) and/or property (properties) of concern and to review the (provisional) classification in the light of all data available.

2. DOSE (CONCENTRATION) - RESPONSE (EFFECT) ASSESSMENT

2.1. The objective shall be to predict the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the predicted no effect concentration (PNEC). (...)

3. EXPOSURE ASSESSMENT

3.1. The objective of the exposure assessment shall be to predict the concentration of the substance which is likely to be found in the environment. That concentration is known as the predicted environmental concentration (PEC). (…)

4. RISK CHARACTERIZATION

4.1. For any given environmental sphere, the risk characterization shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived. If the PEC/PNEC ratio is equal to or less than one, the risk characterization shall result that, at present, no further information and/or testing and no risk reduction measures beyond those which are being applied already are necessary. If the ratio is greater than one, the rapporteur shall judge, on the basis of the size of that ratio and other relevant factors, such as (...) if further information and/or testing are required to clarify the concern or if risk reduction measures are necessary.

The first step is to “predict the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the predicted no effect concentration (PNEC),” but could also be termed a “non-adverse effect threshold.” The concentration of the substance (PEC) that is likely to be found in the environment (PEC: predicted environmental concentration) is then predicted. If this value is lower than the PNEC, it is

anticipated that no adverse effects will occur. If the value is higher, action needs to be taken. This scenario gives rise to a risk reduction strategy, which[15] according to the Regulation, is based on “traditional” chemicals regulation instruments that place restrictions on the marketing and use of a particular substance. The Regulation makes no explicit statement regarding any relationship between its own provisions and those of other regulations. Thus, the resulting regulatory interface problem also remains unresolved at the level of the Existing Substances Regulation.

c)
Committee decisions

Risk reduction strategies are elaborated by Member State rapporteurs on the basis of the Technical Guidance Document on the Development of Risk Reduction Strategies of Dec. 1997.

Pursuant to Article 11 and paragraph 2-3 of Article 15, decisions regarding Existing Substances are taken through a committee procedure[16] that is applied to risk assessment results, proposed strategies pursuant to Article 11 paragraph 2, as well as strategies proposed by the Commission on the basis of the latter strategies and the risk reduction strategy measures therein pursuant to Article 11 paragraph 1.[17]

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[15] The practicability and effectiveness of the currently predominant sequential practice whereby risk potential is first assessed and then risk management measures are decided on should of course be called into question, particularly in view of American experience (Koch/Ashford 2004). In addition, the evaluation process should perhaps be strengthened by informational and other indirect incentive mechanisms (see section E3, p. 72 and section H2d, p. 99).

[16] Article 15 defines a decision making procedure known as comitology whereby the committee reaches a decision pursuant to the procedure stipulated in Article 205 par. 2 EU (formerly Article 148 EC). If the committee and the Commission reach the same decision, the decision is deemed to have been adopted. In the reverse case, the Council decides the issue on the basis of a majority vote. If the Council fails to reach a decision within two months, the decision reverts back to the Commission unless the Council has contravened the Commission by a majority vote (see Roller 2003 and Ginzky 2002, 17)

[17] The committees can turn to two different expert committees for support: the Committee on Technical Risk Assessment and the Committee on Risk Reduction Strategies. There is also a Committee on Competent Government Authorities.

Pursuant to Article 11 paragraph 2, the Commission publishes Risk Assessment Results and proposed risk reduction strategies in the Official Journal of the European Union. Whereas actual Risk Assessment Reports[18] are generally quite comprehensive, the risk reduction results published by the Commission consist of only a brief summary of risk assessments and risk reduction recommendations. On the other hand, the Commission does not publish what are in all likelihood extensive reports on risk reduction potential and the reasons why particular measures have been selected (including the document pursuant to Article 10 paragraph 3 regarding the underlying reasons for risk reduction strategies).[19]

2

Implementation of risk reduction strategy strategies

There is as yet no regulation that determines what happens after the Commission publishes its recommendations.[20] All measures that have been implemented to date are based on Directive 769 which dates back to 1976.[21]

As mentioned previously, the Existing Substances Regulation does not explicitly define the relationship between risk reduction recommendations and the implementation measures engendered by other regulations pertaining to chemicals, installations or environmental media. Hence, there exists no official mechanism that would allow for the “transfer” of results obtained on the basis of chemicals regulations to application domains that are subject to other regulations.

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[18] These compilations are published by the European Chemicals Bureau (ECB) and can be viewed at http://ecb.jrc.it/existing-chemicals/ (Existing Substances Regulation Results).

[19] The Regulation does not expressly require that the Commission publish these documents. Moreover, despite the exhaustive committee decision making process and the involvement of the Scientific Committee, it appears to be somewhat difficult to reach an agreement at the Community level regarding reports as a whole. However, it has been proposed that such reports be published by the competent rapporteur Member State.

[20] Only relatively few recommendations have been published to date (see, among others, Commission 2001: Five Substances; Commission 2004: 11 Substances).

[21] See the case study of Toluene in section D herein as well as Ginzky 2002, 17. *Working Paper on Risk Management in the Framework of Council Directive 76/769/EEC* is relevant here as well, although it is available in draft form only.

Conversely, the latter legislation contains no provisions that would allow for direct transfer of the results of risk assessments and risk recommendations to the Existing Substances Regulation.[22] However, a link of this nature is established in the provision pertaining to the priority substances list in Article 16 paragraph 2 sub-paragraph 1 of the Water Framework Directive, which calls for a "procedure" for "targeted risk-based assessment (following the methodology of Regulation (EEC) No 793/93) focusing solely on aquatic ecotoxicity." This in turn lays the groundwork for a "simplified" test that could also be used [23].

No other legislation helps solve the regulatory interface problem either. For example, the final section of the methodology instructions in the Existing Substances Regulation pertains to the elaboration of risk reduction strategies, but no guidelines are available that explain how such strategies could be implemented, e.g. nothing along the lines of a "Technical Guidance Document on the *Implementation* of Risk Reduction Strategies."

Some risk reduction strategy recommendations employ similar sounding standard phraseology such as this: "Local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected."[24] No instrument is provided for purposes of prognosticating whether the Member States would be able to implement the proposed measures. [25]

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[22] See section E.

[23] (see section E, p. 56]

[24] Risk reduction recommendation 2004, 79, 88 f., 93, 101, 105, 112 and 117 (Toluene). See sections D2d)bb), p.39, and section E1b)aa), p. 59.

[25] This appears to be the case in Germany at any rate according to Christiane Heiss, German Ministry of the Environment, 12 May 2004 (personal communication), and a corroborative comment supplied by Eva Becker, German Ministry of the Environment, 9 June 2004.

D

Case studies of risk reduction

This section contains case studies of three chemicals with a view to shedding light on the risk assessment procedure and ascertaining the scope of the regulatory interface dilemma. Aniline, Toluene and Navy Blue were selected (in consultation with the German Ministry of the Environment) because they allow for the characterization of various sets of regulatory interfaces. Aniline and Toluene are Existing Substances for which a risk reduction strategy report has already been realized at the EU level, while Navy Blue is a New Substance whose use has been banned. However, the manufacturer takes the view that it would have been sufficient to impose downstream user restrictions instead of an outright ban. The case studies are based solely on data that was available as at July 2004, and no subsequent data has been used.

The purpose of risk reduction strategy reports is to elaborate reduction measures for specific substances based on the Technical Guidance Document on Development of Risk Reduction Strategies (TGD-RRS):

> "The rapporteur should develop a risk reduction strategy *tailored to the circumstances* of the *individual* chemical."[26]

In developing a risk reduction strategy, the rapporteur is required to use all available legal risk reduction instruments rather than bringing to bear only those regulations that restrict the marketing and use of the substance in question.

> "To help the rapporteur in this task, much of this document is concerned with describing the wide range of risk reduction options available.[27] (…) Measures fall into a limited number of generic categories, for example (…) controls on emissions.[28] Controls on emissions to air, soil and/or water may also be appropriate if the risks which need to be limited arise from a relatively limited number of point sources.[29]"

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[26] TGD RRS, p. 4, No 1.5 (emphasis added)

[27] TGD RRS, p. 4, No 1.5.

[28] TGD RRS, p. 12, No 3.1.

[29] TGD RRS, p. 12, f., No 3.5.

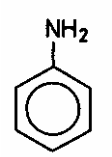
Thus, risk reduction strategy reports identify risk reduction options for specific point sources that are subject to the IPPC and VOC Directives, and also consider matters pertaining to water resources protection and waste water treatment. In addition, issues of soil protection are dealt with indirectly, evaluating sewage sludge as a pathway.

In the following, current risk scenarios and the attendant risk reduction measures are first described. The main focus here is on reduction measures that lie outside the scope of the restrictions on marketing and use currently stipulated by EU legislation,[30] e.g. point source emissions that result from the manufacture of the particular substance. The following question is then addressed: Which substance-specific provisions in current Community legislation apply to these point sources? This then leads to a third question: Does an “instrument gap” exist from the standpoint of the risk reduction that the Existing Substances Regulation aims to achieve? The analysis of regulatory interfaces is then evaluated in section E.

[30] see section F. 2. (Scope of possible restrictions)

1

Aniline



CAS 62-53-3; EINECS No 200-539-3

a)
Risk characterization

Aniline has the largest number of application domains and secondary products, as well as the highest production volume of all the aromatic amines.[31] As an intermediate, it is primarily a component of numerous syntheses that are used for the manufacture of synthetic fibres, rubber (for products such as tires), pharmaceutical products, biocides, and pigments and dyes.[32] The latter application, which gave rise to the discovery of Aniline, has a long tradition, particularly in Germany, where Aniline has been used by BASF[33] since 1897 to synthesize indigo dye, which heretofore had been derived from plants only. Indigo is a natural substance that was first used to manufacture Aniline in 1826.[34] As the number of applications for Aniline has grown, so has its use in Europe, lately from 555,000 t/y in 1993 to an estimated 839,000 t/y in 2003[35]

Over 1000 tons of this Existing Substance are manufactured or used in preparations in the EU each year, thus making Aniline a high production volume chemical (HPVC) pursuant to Article 3. In 1998 76% of the annual production volume of 498,000 tons was used in the most important secondary product of Aniline, which is Methylene Dianiline (MDA).[36]

Aniline, which can be absorbed through the skin, is a potent systemic poison that destroys red blood corpuscles and

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[31] Römpp-Lexikon Chemie (10.), 1, 197.

[32] Aniline RRS, p. 7.

[33] Badische Anilin und Soda Fabrik.

[34] This is also how the substance got its name: Aniline is the Portuguese word for indigo (Römpp-Lexikon Chemie (10.), 1, 197).

[35] Aniline RRS, p. 8.

[36] Aniline RRS, p. 8.

thereby provokes at higher exposition paralysis, including potentially fatal respiratory arrest.[37] There is also evidence that Aniline is carcinogenic (Cat III).[38]

Aniline's vapor pressure of 0.04 kPa (20°C) qualifies it as a volatile organic compound (VOC).[39] This also means that emissions to air (215 t/a) exceed emissions to water (117 t/a). 75% of the Aniline emissions to air are produced by the rubber industry, while 99% of emissions to water are induced by the manufacture and processing of Aniline.[40] The environmentally hazardous effects of Aniline are mainly provoked by waste water since Aniline is highly toxic to aquatic organisms.[41] The manufacture of one ton of Aniline generates 1–10 m^3 of waste water and 0.1–1 kg of COD.[42] In the various environmental compartments the predicted no effect concentration (PNEC) of Aniline are as follows:[43]

$PNEC_{soil}$= 33 µg/kg (dry weight)

$PNEC_{aqua}$ = 1,5 µg/L

$PNEC_{plant}$ = 6 µg/m^3

The available data provide no information regarding Aniline's bioaccumulative properties.[44]

b)
Risk reduction based on chemicals regulations

EU chemicals legislation stipulates the following legal regulations and measures (see Table 1 in the Annex):

1) Classification and labeling pursuant to Council Directive 67/548/EEC:45 there is concern owing to the fact that Aniline may be carcinogenic but cannot be assessed definitively owing to a deficiency of data (R 40, Carc. Cat. 3). The substance may

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[37] Römpp-Lexikon Chemie (10.), 1, 197.

[38] Römpp-Lexikon Chemie (10.), 1, 197.

[39] Aniline RRS, p. 18.

[40] Aniline RRS, p. 9.

[41] Aniline RRS, p. 9, 10.

[42] Aniline RRS, p. 10.

[43] Aniline RRS, p. 9, 10.

[44] Aniline RRS, p. 8.

[45] Directive on classification, packaging and labelling of dangerous substances (Council Directive 67/548/EEC)

give rise to irreversible effects (R 68) and is highly toxic to aquatic organisms (R 50). It has been proposed that Aniline's classification be changed[46] to R 43, "May cause sensitization by skin contact" or R 41 "Risk of serious damage to eyes" (see Table 1, column 1). Other proposals have been made as well.

2) Since Aniline is manufactured or used in amounts exceeding 1000 t/y and is listed in Annex 1 of the Existing Substances Regulation,[47] Article 3 1. of the Existing Substances Regulation applies:

"The manufacturer/importer must submit to the Commission, in accordance with the procedure laid down in Article 6 (2), the following information, as specified in Annex III, within 12 months of entry into force of this Regulation using the computer program provided by the Commission:

a) the name and the EINECS number of the substance;

b) the quantity of the substance produced or imported;

c) the classification of the substance according to Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labeling of dangerous substances(7) or the provisional classification according to the said Directive, including the class of danger, the danger symbol, the risk phrases and the safety phrases;

d) information on the reasonably foreseeable uses of the substance;

e) data on the physico-chemical properties of the substance;

f) data on pathways and environmental fate;

g) data on the ecotoxicity of the substance;

h) data on the acute and subacute toxicity of the substance;

i) data on carcinogenicity, mutagenicity and/or toxicity for reproduction of the substance;

j) any other indication relevant to the risk evaluation of the substance.

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[46] Aniline RRS, p. 18.

[47] OJ No L 84 (1993) p. 9, left column.

Manufacturers and importers must make all reasonable efforts to obtain existing data regarding points (e) to (j). However, in the absence of information, manufacturers and importers are not bound to carry out further tests on animals in order to submit such data."

In other words, 12 months after the Existing Substances Regulation came into force (pursuant to Article 18, the Regulation came into force 60 days after it was published in the Official Journal of the European Union, i.e. on 5 April 1993, plus 60 days = 5 June 1993), which means that as at 5 June 1994 the Commission should have been provided with all of the Aniline-related information required by the Regulation.

3) Inclusion of the substance in the first priority list pursuant to Article 8 paragraph 1 of the Existing Substances Regulation, which stipulates that the Commission "shall regularly draw up lists of priority substances or groups of substances (hereinafter referred to as priority lists) requiring immediate attention because of their potential effects on man or the environment." (for detailed information regarding the priority lists, see Annex, Table 1, column 3).

   After a substance has been listed, the risks associated with it are assessed and a risk reduction strategy is elaborated[48] by the competent Member State (Germany) pursuant to Article 10 of the Existing Substances Regulation.

4) In view of the fact that Methylene Dianiline (MDA) is the most important secondary product of Aniline, the following has been promulgated:

   a ban on the use of MDA in textile and leather goods that could come into direct or lengthy contact with human skin or the oral cavity pursuant to Directive 2003/3/EC[49] (item 9 (azo colorant), point 43). Marketing of the substance is banned for other applications in mass concentrations exceeding 0.1%. Article 2 of this Directive stipulates that the Member States must comply with these restrictions by 30 June 2004 (see Table 1, column 4).

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[48] i.e. the Aniline RRS that is cited in the present document.

[49] Commission Directive 2003/3/EC of 6 January 2003 relating to restrictions on the marketing and use of "blue colorant" (twelfth adaptation to technical progress of Council Directive 76/769/EEC)

c)
Risk reduction based on legislation outside the purview of chemicals regulations

An overview of measures that can be realized pursuant to point source-specific legislation (only future legislation, where applicable) can be found in Table 2 in the Annex. In detail these provisions stem from legislation governing industrial installations and water.

aa) *Provisions governing industrial installations*

Aniline emissions from industrial point sources are subject to the general provisions of the IPPC Directive[50] and the specific provisions of the VOC Directive.

The IPPC Directive stipulates the following:

a) The Member States are required to ensure that Aniline manufacturing and processing is realized in accordance with the general principles governing operators' basic obligations pursuant to Article 3 of the IPPC Directive insofar as manufacturing and processing constitute an industrial activity as stipulated in Article 1, Annex 1 of the IPPC Directive.

   To begin with, the manufacture of Aniline is subject to the aforementioned obligations by owing to the fact that category 4.1.d) of Annex 1 of the IPPC Directive encompasses "Chemical installations for the production of basic chemicals such as nitrogen-containing hydrocarbons, and amine in particular." In contrast to most of the other activities that are categorized in this Annex, the aforementioned obligations do not only apply when a predefined absolute volume threshold is reached, but instead come into play once a particular substance "is produced in industrial quantities through chemical transformation" (No 4 Annex I).

   Consequently, pursuant to Article 3 of the IPPC Directive, wherever Aniline is manufactured in the EU, Member States must ensure (among other things) that all environmental protection measures deploy the best available techniques (Article 3(a) of the IPPC Directive) and that no significant environmental pollution is caused (Article 3(b) of the IPPC Directive).

[50] Council Directive 96/61/EC of 24 September 1996 regarding integrated pollution prevention and control (OJ L 257 v. 10.10.1996, p. 26 – 40).

b) In addition to manufacturing, the processing of Aniline is also governed by regulations of the IPPC Directive insofar as such manufacturing involves chemical transformation on an industrial scale and the attendant activities fall within the purview of Article 1, Annex 1 of the IPPC Directive. These regulations apply to most Aniline processing, which is accounted for by the following: basic plastic materials (polymers, synthetic fibres and cellulose-based fibres; category 4.1.h), synthetic rubbers (category 4.1.i), dyes and pigments (category 4.1.j); basic plant health products and biocides (category 4.4); and basic pharmaceutical products for use in chemical processes such as sulfanilamides (category 4.5).

   Thus, industrial production of Aniline in total, as well as most Aniline processing, is subject to the general principles governing operators' basic obligations pursuant to Article 3 of the IPPC Directive.

c) The use of Aniline is subject to a special IPPC regulation insofar as the integrated IPPC Directive stipulates that a high level of protection for the environment as a whole is to be achieved by means of protection of the air, water and soil (see recitals 7 and 8 in the Directive) and insofar as this objective is to be implemented via permits and (where appropriate) permits subject to specific conditions. In this regard, Article 9, paragraph 3 of IPPC stipulates that "permits must include emission limit values for pollutants, in particular those listed in Annex III, [that are] likely to be emitted from the installation concerned in significant quantities, having regard to their nature and their potential to transfer pollution from one medium to another (water, air and land)." Among the substances listed in Annex III are volatile organic compounds (No 4), including Aniline, which is a high volatile organic compound with a vapor pressure of 0.04 kPa. The use of Aniline, as well as inadvertent Aniline emissions from IPPC-relevant installations in accordance with the permits for such installations (pursuant to Article 9 of IPPC), is also subject to the provisions of IPPC.

Moreover, Aniline emissions from point sources are subject to plant-related regulations via the VOC Directive.[51]

[51] Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations. (OJ L 085, 29 March 1999, p. 1 – 22).

The vapor pressure of Aniline, which as previously mentioned is 0.04 kPa (20°C = 293.15 K), far exceeds the limit value for volatile organic compounds (01 kPa at 293.15 K) stipulated in Article 2 No 17 of the VOC Directive. However, the use of Aniline is covered by the VOC Directive, whose Article 1 defines the Directive's purpose as follows: "The purpose of this Directive is to prevent or reduce the direct and indirect effects of emissions of volatile organic compounds into the environment, mainly into air, and the potential risks to human health, by providing measures and procedures to be implemented for the activities defined in Annex I, in so far as they are operated above the solvent consumption thresholds listed in Annex IIA.[52]

Thus, the Member States are obligated to implement measures that will ensure compliance with the provisions of Article 5 paragraphs 2-12 of the VOC Directive. Accordingly, if Aniline is used for the activities defined in Annex 1 and the use exceeds the threshold values stipulated in Annex II A, the VOC Directive must be implemented via national legislation so as to ensure compliance either with specific emission limit values as per Article 5, paragraph 2(a) or with a reduction plan as per Article 5, paragraph 2(b).

In accordance with its application domain, Aniline is subject to the following VOC Directive regulations:

> "Aniline use shall be governed by the measures and procedures as provided in national legislation and pursuant to Article 1 of the VOC Directive, insofar as the substance is used for the following purposes:

Activities as per Annex I
Rubber conversion
Manufacture of pharmaceutical products

AND insofar as the following solvent consumption thresholds are exceeded:

Thresholds as per Annex II A
For rubber conversion: 15 t/y

[52] There is some controversy as to whether the VOC Directive also applies to substances whose release is provoked by technical conversion processes as vulcanising in the rubber industry (source: Birgit Mahrwald, UBA III 2.4).

For the manufacture of pharmaceutical products: 50 t/y

Compliance with the following emission limits is mandatory:

Emission limits as per Annex II A
For rubber conversion: –20 mg C/Nm³ for waste gas[53] ([1]) However, when technologies are used that allow for the reuse of recovered solvents, an emissions limit of 150 mg C/Nm³ shall apply. – 25% of the solvents used for diffuse emissions from new installations ([2]) This emissions limit shall not apply to solvents used in products or preparations that are sold in closed containers. – 25% of the solvent used as a total emissions limit for both new and existing installations.

For the manufacture of pharmaceutical products: – 20 mg C/Nm³ for waste was ([1]) When technologies are used that allow for the reuse of recovered solvents, an emissions limit of 150 mg C/Nm³ shall apply. – 5% of the solvent used for diffuse emissions from new installations and 15% of the latter for existing installations ([2]) This emissions limit shall not apply to solvents used in products or preparations that are sold in closed containers. – 5% of the solvent used for diffuse emissions from new installations – 15% of the solvent used for diffuse emissions from new installations”

Pursuant to the Existing Substances Regulation, Article 5 paragraph 13 of the VOC Directive contains the following reference to the risk assessment and reduction process:

> “Where a risk assessment is carried out in accordance with Council Regulation (EEC) No 793/93 (11) and Commission Regulation (EC) No 1488/94 (12) or Council Directive 67/548/EEC and Commission Directive 93/67/EEC (13) of any of the substances causing the labeling R40, R60 or R61 which are controlled under this Directive, the Commission shall consider

[53] The rapporteur (Germany) made the following remark about this item in the RRS Aniline document without explaining the reasons for his statement: “It is predictable that this sum parameter will not meet the effect based standard of the $PNEC_{plant}$ of 6 µg/m³ for Aniline releases into the air. The VOC Directive is not suitable to reduce the risk effectively to local air caused by the production site and the downstream users in the caoutchouc industry.” (RRS Aniline, p. 18, f.)

the conclusions of the risk assessment and shall take the necessary measures as appropriate."

Aniline is classified as a substance for which there is "limited evidence of a carcinogenic effect" (R 40). A risk assessment pursuant to the Existing Substances Regulation is also realized, thus complying with the applicable risk assessment requirements. The Commission has to review the risk assessment and to undertake the necessary measures.

The IPPC and VOC Directives contain air emissions regulations that apply to both new and existing installations and thus also help to reduce risk.

The VOC Directive explicitly refers to the Community risk assessment procedure but fails to specify a concrete protection goal, nor does it indicate which risk reduction measures the Commission should undertake. However, this gap is filled by Article 1 of the VOC Directive which states that the Directive's purpose is to "prevent or reduce the direct and indirect effects of emissions of volatile organic compounds into the environment, mainly into air, and the potential risks to human health." However, the Directive does not specify the extent to which implementation of this goal should exceed the scope of the stipulations in the Annexes.

bb) *Water legislation*

Community water legislation[54] has not yet explicitly provided for Aniline emissions limits. Moreover, despite the fact that Aniline has been classified as "very toxic to aquatic organisms," (R 50), it has not yet been added to the "list of priority substances in the field of water policy" in Annex X of the Water Framework Directive[55] . However, since Aniline has been classified as a substance of concern owing to its possible carcinogenic effects in humans, which cannot be assessed definitively owing to a deficiency of data

[54] Directive of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (Water Framework Directive) (OJ L 327 v. 22.12.2000, p. 1 – 73).

[55] See "Decision No 2455/2001/EC of the European Parliament and the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive," OJ L 331, p. 1 – 5.

(Carc. Cat.3), it falls under the purview of the following provision:

> Annex VIII (INDICATIVE LIST OF THE MAIN POLLUTANTS)
>
> 4. "Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment."

The Working Group of the Federal States on Water Problems (Länderarbeitsgemeinschaft Wasser LAWA) has adopted Aniline as a candidate substance for Annex VIII of the WFD.

d)
Recommendations based on the Existing Substances Regulation

The Commission has not yet published any Aniline risk reduction recommendations based on the Existing Substances Regulation.[56] The overall processing status for the 144 priority chemicals was described as follows in July 2004:[57]

> "On a total of available files: 141 RAR status, 73 Drafts RAR, 41 Summaries (for 44 substances), 41 Final Reports (for 44 substances), 1 Addendum, 81 Conclusions, 17 OJ Recommendations."

The environmental recommendations in the Existing Substances Regulation stem from previous phases only, i.e. the risk assessment report, the evaluation of the latter by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) and the risk reduction strategy (RRS Aniline) proposed by the rapporteur (Germany).

aa) *The Risk Assessment Report and the CSTEE*

The CSTEE[58] has requested that further Aniline toxicity tests on soil organism be conducted in order to ensure that implementation of the parameters stipulated by the Risk Assessment Report will maintain the critical PEC/PNEC = 1

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[56] http://ecb.jrc.it/existing-chemicals/ (11.07.2004).

[57] http://ecb.jrc.it/esis/esis.php?PGM=ora&DEPUIS=autre (11.07.2004).

[58] in March 2004 renamed as "SCHER": Scientific Committee on Health and Environmental Risks (SCHER)

ratio.[59] The Committee also requested that a series of other tests be realized, as follows:

> "Due to the high solubility, water must be assumed to be the compartment of major concern.[60] (…) Some data are available on aquatic organisms although some were obtained using unsuitable methodology (static tests, nominal concentrations etc.). Therefore a careful reliability check is needed.[61] (…) Although there is experimental evidence of severe damage to terrestrial plants from atmospheric exposure to Aniline, the CSTEE agrees with the conclusion of the RAR that relevant information is missing in these experiments. Hence a NOEC is not reported and a PNEC cannot be calculated. Considering the evidence of a potential risk, additional tests are required.[62] … In view of the high level of volatility involved, bio-concentration studies on plants are also recommended.[63]"

Despite the report's view (stated twice) that "relevant information" is missing, the CSTEE completely rules out the possibility that Aniline might be a risk for the aquatic food chain:

> "Due to the low bio-accumulation potential, the CSTEE agrees with the assumption that a risk for the aquatic food chain, including fish eating higher vertebrates (mammals and birds), can be excluded."[64]

The CSTEE also states that there is not sufficient evidence available to ascertain the extent to which Aniline might be carcinogenic in humans:

> "A general problem with the repeated-dose toxicity studies with Aniline is that a clear NOAEL has not been identified, either due to the selection of too high doses or to other deficiencies in study planning and conduct.[65] … Available epidemiological data are inadequate to allow a conclusion as to the carcinogenicity of Aniline in humans. Cases of bladder tumours among Aniline dye workers are reported. However, these workers were generally exposed to a number of different aromatic amines including Aniline, Alpha- and Beta-naphthylamine, Benzidine and

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[59] CSTEE Aniline Environment, p. 2, 4.

[60] CSTEE Aniline Environment, p. 3.

[61] CSTEE Aniline Environment, p. 4.

[62] CSTEE Aniline Environment, p. 4.

[63] CSTEE Aniline Environment, p. 5. (Translator's note: cited passage edited for reasons of clarity)

[64] CSTEE Aniline Environment, p. 5.

[65] CSTEE Aniline Human Health, p. 4.

> Auramine, and there is no sufficient evidence to suggest that Aniline itself has caused the bladder tumours.[66] The mechanism of tumour formation and its relevance for humans is presently unclear. In particular, there is not sufficient evidence to postulate a threshold mechanism and hence Aniline was considered to be a non-threshold carcinogen by the member states' rapporteur. It is possible that erythrocyte toxicity and the ensuing splenic toxicity may afford a promotive stimulus for tumour formation. However, since a genotoxic mechanism cannot be discounted, the CSTEE supports the conclusion that Aniline cannot be classified as a threshold-type carcinogen.[67] It is not known whether Aniline is generally used as a component in consumer products.[68] The CSTEE agrees with the view that there are concerns for all occupational exposure scenarios, though there are uncertainties concerning the mechanism of tumour formation and its relevance for humans. However, the CSTEE points to the considerable uncertainties underlying the carcinogenic risk assessment of Aniline exposure presented in the RAR.[69]

The CSTEE's position is as follows, particularly in light of the acute and chronic toxicity, as well as the carcinogenicity of Aniline in humans:

> "The CSTEE agrees with the RAR conclusions that risk reduction measures have to be initiated and that occupational exposure limits should be reconsidered."[70]

bb) *Risk reduction strategy proposed by the competent rapporteur (Germany)*

The rapporteur's risk reduction strategy contained the following recommendations for the reduction of Aniline-induced environmental risk:

> "Emission Limit Values and Environmental Quality Standards
>
> ELVs and/or EQSs could be implemented under the following legal instruments at EU level:
>
> - Water Framework Directive 2000/60/EC (environmental quality standards, emission limit values)
> - IPPC Directive 96/61/EC (definition of best available technology)

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[66] CSTEE Aniline Human Health, p. 5.

[67] CSTEE Aniline Human Health, p. 7.

[68] CSTEE Aniline Human Health, p. 8.

[69] CSTEE Aniline Human Health, p. 8.

[70] CSTEE Aniline Human Health, p. 3.

– National measures (definition of best available technology and/or ELVs).” [71]

According to the rapporteur, this would entail the following:

> “To reduce the Aniline specific risks for the environment it is necessary to reduce and control the emissions of production and processing sites to water and air.
>
> Reduction of emissions to water and air can be achieved by implementing BAT techniques. In addition, emissions controls should be implemented either by ELVs or by EQS so as to ensure that operators comply with the substance-specific PNEC of Aniline for water and air. ELVs and EQSs can be determined at the national and EU levels if Community wide action is required. Local aquatic and atmospheric emissions of Aniline should be governed by national rules so as to ensure that the possibility of environmental risk is ruled out.
>
> Local authorities should implement risk reduction measures in accordance with the IPPC’s timeline. In addition, national authorities should include the PNEC of Aniline in their river basin management plans and should develop a monitoring strategy.
>
> It is recommended that the Member States carefully monitor the implementation of BAT by permitting and should notify the Commission of any significant developments regarding the reduction of Aniline emissions within the framework of information exchange on BAT.
>
> If Aniline-specific risks are still present after the implementation deadline has expired, the Commission should propose harmonized EU wide EQS for Aniline under the IPPC Directive.”[72]

e)
Obstacles to implementation

In view of the absence of sufficient data, as mentioned repeatedly by the CSTEE, it is clear that the goal defined in Article 1(1)(a) of the Existing Substances Regulation in regard to gathering data on Aniline has not been achieved to a satisfactory degree. Although the Regulation stipulates that this data should be submitted to the Commission by mid-1994, ten years after this deadline has expired the data is

[71] Aniline RRS, p. 20.

[72] Aniline RRS, p. 28, 29.

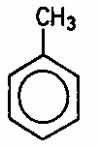
still incomplete. This constitutes a second-order implementation deficit.

The rapporteur’s proposed risk reduction measures refer to mechanisms from other sectoral regulations (see section E).

The following first- and second-order regulatory interface problems can be said to exist:

- There is no clearly defined mechanism at the legislative level that would allow for the interaction between chemicals regulations and environmental legislation governing other sectors.
- This lack is reflected on the administrative level in that risk reduction strategies pertaining to chemicals regulations are elaborated without any clear idea as to the extent to which risk reduction instruments from other regulations can be applied.

2
Toluene



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

a)
Risk characterization

Toluene is widely used in the chemical industry as a solvent and base product for the manufacture of numerous organic compounds such as benzene, phenol, benzoic acid, dyes, pigments and so on. Toluene is also a constituent of many end user products such as coatings, adhesives, ink and so on.[73] (see Figure 1).

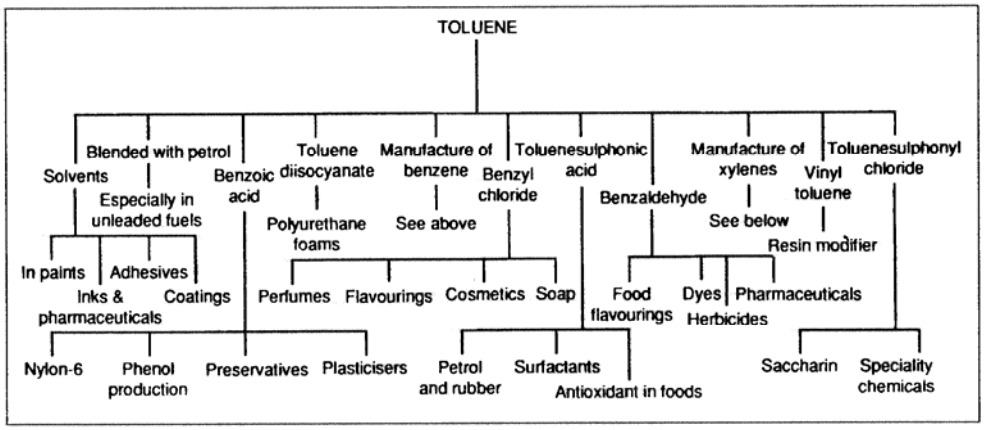


Figure 8.2: Uses of toluene
[EC DGXI, 1993 #8]

Figure 2: Uses of Toluene (source: LVOC BREF, p. 196).

It is estimated that the European chemical industry used 2.8 million tons of Toluene in 1995. Toluene is classified as an HPVC in accordance with Article 3 of the Existing Substances Regulation.[74] Non-isolated Toluene is also used in fuels and

[73] RRS Toluene, p. 17.

[74] RRS Toluene, p. 8.

occurs in average concentrations of 11.4%.[75] If total European fuel consumption is assumed to be approximately 120 million t/year, it would mean that approximately 14 million tons of Toluene are used in Europe each year. The 2.8 million tons of Toluene used by the chemical industry each year account for only 16% of total Community consumption of Toluene.[76]

Toluene vapors, which have an agreeable aromatic odour, induce a narcotic effect when inhaled in high concentrations and can also provoke eye or respiratory tract inflammation.[77] The amount of Toluene inhaled is determined by lung activity.[78] Repeated inhaling of Toluene can lead to central nervous system and inner ear damage, which is associated with an elevated risk of partial hearing loss in the high-frequency range.[79] In addition, in laboratory studies of male rats, sperm count decreased following exposure to concentrations of 2000 ppm (7600 mg/m^3) of Toluene. There is also some empirical evidence (based on relatively little data) that dosage levels of 88 ppm (330 mg/m^3) can induce spontaneous abortions.[80] This is the lowest adverse effect concentration (LOAEC) for which harmful effects on human reproduction have been observed.[81] Eye or skin contact with liquid Toluene (which can be absorbed by the skin) provokes irritation in these structures.[82] Toluene is deposited throughout the body, with the highest concentrations occurring in the fatty tissues.[83]

Like Aniline, Toluene is a volatile organic compound. Toluene emissions during production, processing and use are mainly to air. Owing to Toluene's high vapor pressure, soil and water emissions of the substance also eventually make their way into the air.[84] In the absence of comprehensive

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[75] RRS Toluene, p. 8.

[76] RRS Toluene, p. 8.

[77] Römpp-Lexikon Chemie (10.), 6, 4579.

[78] RRS Toluene, p. 17.

[79] RRS Toluene, p. 18.

[80] RRS Toluene, p. 19.

[81] RRS Toluene, p. 19.

[82] Römpp-Lexikon Chemie (10.), 6, 4579.

[83] RRS Toluene, p. 17.

[84] RRS Toluene, p. 9.

installation-specific data, Toluene emissions have been estimated to be as follows:

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

Figure 3: Estimated Toluene emissions (source: RRS Toluene, p.10).

The relatively little installation-specific data available shows that most Toluene emissions occur when the substance is being manufactured, with emissions to air ranging from 0 up to about 7000 kg/day. Installations that produce and process Toluene release between 0.08 and approximately 1000 kg/day to the atmosphere and from 3 to 1600 kg/day to the hydrosphere.[85] The PNECs for the various environmental compartments are as follows:[86]

– PNEC $_{soil}$= 0.3 mg/kg

– PNEC $_{aquatic\ organisms}$ = 0.074 mg/L

– PNEC $_{micro\text{-}organisms}$ = 8.4 mg/L

It is thought to be unlikely that Toluene has bioaccumluative properties.[87]

b)
Reduction of risk from Toluene as provided in chemicals regulation

According to current Community chemicals legislation, Toluene (an Existing Substance) is subject to the following regulations and instruments (see Table 1 in the Annex):

[85] RRS Toluene, p. 9 (default values were used to arrive at this figure in some cases)

[86] RRS Toluene, p. 12, f. .

[87] RRS Toluene, p. 10.

1) Classification and labeling pursuant to 67/548/EC, although Toluene is classified only as highly flammable and a health hazard. However, in light of recent data, a reclassification is planned that will mention the possible risk of harm to the unborn child (R 63, Repr. Cat. 3) and will indicate that lengthy exposure can be very harmful by inhalation (R 48/20)[88] (see Table 1, column 1).

   Since Toluene is manufactured or used in amounts exceeding 1000 t/year and is listed in Annex 1 of the Existing Substances Regulation,[89] Article 3.1 of the Existing Substances Regulation also applies to Toluene. This means that, as with Aniline, the submission deadline for Toluene risk data was 5 June 1994.

2) Toluene is included in the second priority list pursuant to Article 8 paragraph 1 of the Existing Substances Regulation, which stipulates that the Commission "shall regularly draw up lists of priority substances or groups of substances (hereinafter referred to as priority lists) requiring immediate attention because of their potential effects on man or the environment" (for detailed information regarding the priority lists, see Table 1, column 3).

   Pursuant to Article 10 of the Existing Substances Regulation, a risk assessment has been carried out and a risk reduction strategy has been elaborated[90] for Toluene by the competent Member State (Denmark).

c)
Risk reduction based on legislation outside the purview of chemicals regulations

Like Aniline, Toluene is subject to various laws and legal regulations that fall outside the purview of chemicals regulations (see Table 2 in the Annex).These laws are as follows:

[88] RRS Toluene, p. 22.

[89] OJ No L 84 (1993) p.15, right column.

[90] This refers to the RRS Toluene document cited herein.

aa) *Provisions governing industrial installations*

Toluene point-source emissions (like those of Aniline) are subject to industrial installation regulations as well as the provisions of the IPPC Directive and VOC Directive.

IPPC Directive

Industrial production of Toluene in petroleum and gas refineries pursuant to Article 1 No 1.2 in Annex 1 of the IPPC Directive is subject to the general principles governing operators' basic obligations pursuant to Article 3 of the IPPC Directive. Inasmuch as Toluene is a natural component of crude oil that is extracted during the petroleum refining process, the substance is mainly produced in petroleum and gas refineries.[91] The use of Toluene is also subject to the aforementioned operators' obligations insofar as the production process yields a compound pursuant to No 4.1 of the Annex of the IPPC Directive. Toluene is used for a broad range of applications, and thus many of the compounds mentioned here are derived from this substance (see Fig.1).[92]

Since Toluene is also classified as a volatile organic compound in accordance with Annex III No 4 of the IPPC Directive, plant approval procedures in accordance with Article 9 paragraph 3 of the IPPC Directive must also comply with the applicable emissions limits.

VOC Directive

In addition, since Toluene is classified as a volatile organic compound by Article 2 No 17 of the VOC Directive, Toluene point source emissions are also subject to this Directive. Accordingly, the Member States are required to enforce the provisions of Article 5 paragraphs 2-12 of the VOC Directive insofar as Toluene is used for the activities defined in Annex 1 of the Directive and such use does not exceed the threshold values defined in Annex II A. In accordance with its application domain, Toluene is subject to the following provisions of the VOC Directive:

> "Toluene use shall be governed by the measures and procedures as provided in national legislation, pursuant to Article 1 of

[91] RRS Toluene, p. 1, 29.

[92] RRS Toluene, p. 29.

the VOC Directive, and insofar as the substance is used for the following applications:

Activities as per Annex I
Printing: Any reproduction activity of text and/or images in which, with the use of an image carrier, ink is transferred onto whatever type of surface.
Adhesive coating:[93] Any activity in which an adhesive is applied to a surface, with the exception of adhesive coating and laminating associated with printing activities.

AND if the following solvent consumption thresholds are exceeded:

Thresholds as per Annex II A
For the various printing processes mentioned in No 1 – 3: 15 - 30 t/year
For adhesive coatings: 5 t/year

Hence, the following emissions limits apply:

Emission limits as per Annex II A
For the various printing processes: – between 20 and 100 mg C/Nm for waste gas – between 20 and 30% of the solvent used for diffuse emissions depending on the process and the age of the installation.
For adhesive coatings – 50 mg C/Nm for waste gas ([1]) When technologies are used that allow for the reuse of recovered solvents, an emissions limit of 150 mg C/Nm³ shall apply. – 25% of the solvent used for diffuse emissions in new installations, providing that solvent consumption does not exceed 15 t/year; – Only 20% of the solvent used for diffuse emissions in new installations if solvent consumption exceeds 15 t/year.”

In contrast to Aniline, Toluene is not subject to the provisions (cross references) of Article 5 paragraph 13 of the VOC Directive. In accordance with Article 5 paragraph 13 of the VOC Directive, a risk assessment as required by Commission Directives (EC) No 793/93 and (EC) No 1488/94 was also realized for Toluene. According to the results of this risk assessment, Toluene (unlike Aniline) is not subject to

[93] This application is not included in the Commission’s proposed ban (COM (2004) 320) of 28 April 2004 because the latter document only provides for a ban on toluene, which is a component of consumer adhesives.

any of the following R 40 classifications pursuant to Article 5 paragraph 13 of the VOC Directive: R 40: “Limited evidence of a carcinogenic effect;” R 60: “May impair fertility;” and R 61: “May cause harm to the unborn child.” The competent Commission committee recommended that Toluene be reclassified and labelled as an R 63 risk (Repr. Cat. 3), viz. “Possible risk of harm to the unborn child.”[94]

bb) *Water legislation*

Like Aniline, Toluene has not yet been added to the “list of priority substances in the field of water policy” in Annex X of the Water Framework Directive.[95] In view of the proposal to reclassify Toluene as an R 63 risk (“possible risk of harm to the unborn child”), it might be advisable to subsume Toluene under the following provision:

> Annex VIII (INDICATIVE LIST OF THE MAIN POLLUTANTS)
>
> 4.“Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment.”

d)
Recommendations from the Existing Substances Regulation

aa) *Risk reduction strategy proposed by the rapporteur (Denmark)*

The risk reduction strategy proposed by Denmark makes the following recommendations:[96]

- “ (...) to take effective measures to ensure that no risk is expected in receiving water systems of Toluene
- European Commission should urge Member States in accordance with directive 76/464/EEC to take effective measures to ensure that no risk is expected in receiving water systems of Toluene
- a recommendation that specify that the concerned industrial sector and respective abatement technology should be

[94] RRS Toluene, p. 22.

[95] See “Decision No 2455/2001/EC of the European Parliament and the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive,” (OJ L 331, p. 1 – 5).

[96] RRS Toluene, p. 53.

included in the forthcoming work on the respective BREF (IPPC)
- If these measures prove to be not effective and reports identify ongoing emissions, national-wide EQS or Community-wide uniform emission limit value should be established under the WFD.
- Because it is expected to take a long time until the described EU-wide measures will show an effect, appropriate national measures should be taken as soon as possible (detailed installation of specific technical measures and/or emission limit values derived form BAT/BEP)
- Limit value for Toluene in air/reduction of Toluene emission in accordance to the VOC-directive."

bb) *The Commission's risk reduction recommendations*

Unlike Aniline, for Toluene the Commission has already elaborated risk reduction recommendations (2004/394/EC of 20 April 2004) pursuant to the risk assessment and risk reduction strategies for 11 substances including Toluene.[97]

The Commission proposed the following changes in chemicals regulations in regard to Toluene:

"It is recommended,

- to consider at Community level marketing and use restrictions in Directive 76/769/EEC for the substance as such or in preparations for use in adhesives and spray paint.
- The marketing and use restrictions proposed will eliminate the need for more information on reproduction as a consequence of inhalation exposure."[98]

In this regard, the Commission has drawn up a draft Directive on the marketing and use of Toluene (twenty-eighth amendment of Directive 76/769/EC).[99] This Directive would prohibit the marketing and use of Toluene as a component of any chemical preparations whose mass concentration is 0.1% or more of adhesives or spray paints. In taking this action, the Commission stopped short of exercising its power to impose a total ban on Toluene, which the wording of the recommendation ("restrictions for the substance as such") would have allowed.

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[97] Risk reduction recommendation 2004.

[98] Risk reduction recommendation 2004, p. L 144/117.

[99] COM (2004) 320 (final)

The Commission's recommendations for restrictions on Toluene emissions under industrial installation regulations are as follows:

> "It is recommended,
>
> – to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) 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.
> – local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected."[100]

The Commission proposed the following in regard to point source Toluene emissions to waste water:

> "It is recommended, that(…) the European Commission should consider the inclusion of Toluene in the priority list of Annex X to Directive 2000/60/EC (Water Framework Directive) 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, so as to ensure that concentrations in surface water systems do not exceed the quality objective."[101]

e)
Obstacles to implementation

In view of the fact that this substance, which may be harmful to unborn children, is emitted in large amounts on a regular basis (see Fig. 2), efficacious risk reduction measures, as well as other effective measures, are needed.

aa)
Proposed Commission Directive COM (2004) 320

The Commission's proposed use restrictions (COM (2004)) meet the aforementioned effectiveness criterion. However, the proposed Directive bans the use of Toluene only in certain

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[100] Risk reduction recommendation 2004, L 144/117.

[101] Risk reduction recommendation 2004, L 144/117.

coatings and adhesives, pursuant to the following conditions:

- Spray paint is the only type of coating included in the ban
- The restrictions apply to consumer products only and not to professional products, i.e. products that are used for commercial purposes can still contain Toluene (e.g. adhesives used by carpet and flooring installers).
- In these products, the mass concentration of Toluene is still limited to <0.1% (i.e. 1 kg of product may not contain more than 0.99 g of pure Toluene).

According to the Danish environmental protection agency, this ban will not reduce the number of exposure scenarios by a significant amount (i.e. the use of Toluene in spray paints and adhesives).[102] The far more prevalent uses of Toluene are excluded from the Commission's proposed Directive, as are the attendant protective mechanisms for humans and the environment.

In short, the proposed ban on the use of Toluene pertains to a portion of the identified risks only.

bb)
Risk reduction measures outside the purview of chemicals legislation

In terms of the risk reduction measures that fall outside the purview of Community chemicals regulations, it remains unclear how measures pertaining to identified risk reduction strategies can be used to promote compliance with the relevant regulatory frameworks. In this sense, a regulatory interface problem can be said to exist at the legislative level (first-order implementation deficit), which is likely to result in a second-order (administrative) implementation deficit.

[102] RRS Toluene, p. 17.

3
Navy Blue

Navy Blue, which is marketed under a number of other names,[103] consists of two components that both contain chrome (a heavy metal). Since only one of the two components of Navy Blue has been assigned a CAS number, the substance is only identifiable via its molecular formula and the systematic names of its components.

	Component 1	Component 2
Molecular formula	$C_{39}H_{23}ClCrN_7O_{12}S.2\ Na$	$C_{46}H_{30}CrN_{10}O_{20}S_2.3\ Na$
Name	Dinatrium-(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chlor-2-oxido-phenylazo)-2-naphtholato)chromat(1-)	Trinatrium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromat(1-)
CAS No.	118685-33-9	

Fig. 4: components of navy blue

The mixture forms a metal complex containing two azo groups. Navy Blue is used as a wool and polyamide dye, and because of its excellent light resistance properties, it is often used in auto upholstery fabric.[104] Navy Blue is not listed in EINECS. Unlike Toluene and Aniline, Navy Blue is by definition a new substance pursuant to Article 3 No 3 of the German Chemicals Act (ChemG). Consequently, the information gathering, risk characterization and risk reduction procedures for Navy Blue are all subject to the New

[103] e.g. azul marinho 018112, bleu marine 018112, navy 018112, navy blue 018112; in: English language version of the 7th (draft) edition of Elincs (http://ecb.jrc.it/new-chemicals/), 16 May 2004. The substance is also called Lanasyn-Marineblau S-BL in the ISIS/Base database.

[104] Navy Blue fact sheet, p. 1.

Substances Regulation, which differs entirely from the Existing Substances assessment system.

a)
Risk characterization under the New Substances Regulation

In accordance with the new Regulation, New Substances are subject to a prospective rather than a retrospective assessment that identifies risks for users, consumers and the environment. New Substances regulations are mainly realized as Directives, which are binding but whose form and method of implementation are left up to each Member State (Article 249 paragraph 3 EC)[105]. The first Directive of this type was the sixth amendment to Directive 67/548/EC, which stipulates the following in Article 5 paragraph 1 of Directive 79/831/EC:[106]

> "The Member States shall take all the measures necessary to ensure that without prejudice to Article 8 substances cannot be placed on the market (...) unless the substances have been notified to the competent authority of one of the Member States in accordance with this Directive (...)"

In accordance with this Directive, Article 4 of the German Chemicals Act (ChemG) now requires that such substances be registered before being placed on the market. Pursuant to other Directives, including Directive 92/32/EC[107] (which is the seventh amendment to Directive 67/548/EC) and Article 6 paragraph 1 No 11 of the German Chemicals Act (ChemG) such registrations must be accompanied by test certifications in accordance with the requirements of the so called basic test. Pursuant to Article 7 of the German Chemicals Act (ChemG), the following test certifications must be provided:

1. Physical, chemical and physico-chemical properties

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[105] The Existing Substances Regulation mainly employs Regulations, which are "binding in [their] entirety and directly applicable in all Member States" (Article 249(2) EC).

[106] Council Directive 79/831/EC of 18 September 1979 amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ No L 259 of 15.10.1979, p. 10 – 28

[107] Council Directive 92/32/EC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ No L 154 of 05.06.1992, p. 0001 – 0029.

2. Acute toxicity

3. Any evidence that the substance is carcinogenic or mutagenic

4. Any evidence that the substance impairs fertility

5. Any evidence that the substance causes irritation or dermal corrosion

6. Any evidence that the substance may cause sensitization

7. Any evidence of subacute toxicity

8. Any evidence that the substance degrades abiolgically and biodegrades readily

9. Any evidence of the rapid onset of toxicity to aquatic organisms

10. Any evidence that the substance inhibits algae growth

11. Any evidence of bacteria inhibition

12. Any evidence of adsorption or desorption

Article 6 of Directive 92/32/EC stipulates the following in the interest of ensuring that this information is provided to the competent authorities:

> "Manufacturers, distributors and importers of dangerous substances which appear in the EINECS but which have not yet been introduced into Annex I shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances."

Article 7 paragraph 1 of Directive 92/32/EC stipulates that a technical dossier must be submitted containing the following elements:

> "(...) the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing all available relevant data for this purpose (...) [and additionally] a declaration concerning the unfavourable effects of the substance in terms of the various foreseeable uses."

The actual risk assessment is realized on the basis of the notification that has been submitted, pursuant to the following provisions of Directive 92/32/EC:

> Article 16
>
> Rights and duties of the authorities

1. Member States shall appoint the competent authority or authorities responsible for receiving the information provided for in Articles 7 to 14 and examining its conformity with the requirements of this Directive.

Moreover, if it can be shown to be necessary for the evaluation of the risk which may be caused by a substance, *the competent authorities may ask for further information, verification and/or confirmatory tests concerning the substances or their transformation products*[108], of which they have been notified or have received information under this Directive; (...)

Additionally, the competent authorities may:

- carry out such sampling as is necessary for control purposes (...)

In the case of substances notified in accordance with Articles 7 (1) and 8 (1) and (2), the competent authority which received notification shall carry out an assessment of the risks in accordance with the general principles laid down in Article 3 (2). The assessment shall include recommendations on the most appropriate method for testing the substance and, where appropriate, also include recommendations on measures which will enable the risk for man and the environment in connection with the marketing of the substance to be lessened. (...)

With the Commission's participation pursuant to Articles 17 and 18 of Directive 92/32/EC, pursuant to Directive 93/67/EC[109], the risk assessment process culminates in the attribution of a risk classification as defined under Article 3 of the Directive:

Article 3 of Directive 93/67/EC – Principles of risk assessment

- The substance is of no immediate concern and need not be considered again until further information is made available in accordance with Article 7 (2), 8 (3), 8 (4) or 14 (1) of Directive 67/548/EEC.
- The substance is of concern and the competent authority shall decide what further information is required for revision of the assessment but shall defer a request for that information until the quantity placed on the market

[108] Emphasis added.

[109] Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC, OJ 1993, No L 227, p. 9 - 18.

reaches the next tonnage threshold as indicated in Article 7 (2), 8 (3) or 8 (4) of Directive 67/548/EEC.
- The substance is of concern and further information shall be requested immediately.
- The substance is of concern and the competent authority shall immediately make recommendations for risk reduction.

b)
Risk characterization of Navy Blue under the New Substances Regulation

Application of the provisions of the New Substances Regulation has produced the following results:[110]

Navy Blue was first registered in Switzerland in 1990 and accordingly by companies whose head offices were located outside the EU. The substance has since been registered in eight Member States, including Germany. No summarized production volume data is available for Navy Blue. A maximum of 10 t/year sales volume is indicated in the registrations, which means that total European sales volume is probably between 9 and 90 t/year.

The results of the basic test indicated that Navy Blue could be an environmental hazard. The registrant was asked to carry out additional tests immediately with a view to assessing the aforementioned risk.

According to the results of these additional tests, oral uptake of Navy Blue to rats in some cases led to multiple changes in the animals' red blood cells, clearly discernible cytoxicity, and blue coloration of the internal organs. Evidence of mutagenic and carcinogenic properties was also found. Navy Blue is highly toxic to fish (LC_{50} = 0.07 mg/L) and is classified as an environmentally hazardous substance by the German Chemicals Act (ChemG; Article 3a paragraph 2), which defines an environmentally hazardous substance as follows:

A substance which induces, or whose transformation products induce, any changes in the properties of the ecosystem or in water, soil, air, climate, animals, plants or micro-organisms, that could have an immediate or delayed hazardous effect on the environment.

[110] The section below is documented in a 1994 assessment report that is on file at the German Ministry of the Environment

Navy Blue reaches the environment (surface water) via waste water from textile installations as well as numerous diffuse sources stemming from all usage levels (manufacture, formulation, and preparations). Even when used in accordance with the applicable regulations, such contamination is unavoidable owing to the fact that not all of the dye used in textiles is fixed to the fibers. The non-fixed dye, or residual liquor, reaches the environment via waste water treatment plants where it can only be eliminated in part as it is does not degrade readily. Thus, if Navy Blue is used in the recommended concentrations, it will inevitably pollute surface waters and will harm the aquatic organisms therein. Discharge monitoring is probably not a viable solution to this problem since most Navy Blue is generated by SMEs, which means that discharge comes from numerous direct and indirect sources that are not amenable to monitoring.

Since Navy Blue is not very volatile, emission to air does not come into play. No data is available for either the aquatic or terrestrial compartment because under the New Substances Regulation, assessment of these factors is only required for production volumes of upwards of 100 t/year pursuant to the level 1 “additional” test required by Article 9 of the German Chemicals Act (ChemG). The predicted no effect concentration (PNEC) for Navy Blue is estimated to be $PNEC_{aqua}$ = 1.6 µg/L. However, the predicted environmental concentration (PEC) for Navy Blue is far higher, thus pushing the PEC/PNEC ratio beyond 1 to approximately 1.9. An initial substance assessment led only to conclusion ii) pursuant to Article 3 of Directive 93/69/EC. However, in this case all possible ways to minimize environmental discharge of Navy Blue were explored exhaustively with the user by means of additional data that was provided. But inasmuch as, following the conclusion of this dialogue phase, it was felt that, from a technical standpoint, the risk assessment (PEC/PNEC >1) was unlikely to change, conclusion iv) was adopted. It is against this backdrop that a total prohibition on the use of Navy Blue has been proposed.

c)
Risk reduction based on chemicals regulations

The following risk reduction measures for Navy Blue have been implemented under the New Substances Regulation:

aa) *Classification and labeling of the substance pursuant to Directive 67/548/EC*

Navy Blue is classified as follows:

R 50	Very toxic to aquatic organisms
R 53	May cause long-term adverse effects in the aquatic environment
R 43	May cause sensitization by skin contact[111]

bb) *Total ban under Directive 76/769/EC*

In accordance with the results of the assessment of Navy Blue pursuant to Article 3(iv) of Directive 93/67/EC), public authorities recommended that a total ban be imposed on the use of Navy Blue under Directive 769/76/EC via the adoption of Commission Directive 2003/3/EC,[112] which states as follows:

> The risks to the health and environment of "blue colorant Index No 611-070-00-2" have been assessed under Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for the assessment of risks to health and the environment of substances notified in accordance with Council Directive 67/548/EEC (5); the risk assessment identified a need for reducing risks of the blue colorant to the environment as this blue colorant has a high aquatic toxicity, is not easily degradable and reaches the environment via waste water.[113]

In order to protect the environment the placing on the market and the use of the blue colorant should be prohibited for coloring textile and leather articles. The blue colorant should therefore be added to those substances listed in Annex I to Directive 76/769/ EEC.[114]

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[111] 7th edition of ELINCS (http://ecb.jrc.it/new-chemicals/) of 16 May 2004. This table is preceded by the following remark: "No legal status. Neither the Commission of the European Communities nor any person acting on behalf of the Commission is responsible for the use which might be made of the following information."

[112] Commission Directive 2003/3/EC of 6 January 2003 relating to restrictions on the marketing and use of "blue colorant" (twelfth adaptation to technical progress of Council Directive 76/769/EEC), OJ No L 4 of 09.01.2003, p. 12 - 15.

[113] Recital No (2) of Directive 2003/3/EC.

[114] Recital No (3) of Directive 2003/3/EC.

In accordance with this proposal, Navy Blue was added (as No 1) to the “List of azo dyes” in the Annex to the Directive (see fig. 4).

List of azodyes

	CAS number	Index number	EC number	Substances
1	Not allocated Component 1: CAS-No: 118685-33-9 $C_{39}H_{23}ClCrN_7O_{12}S.2Na$ Component 2: $C_{46}H_{30}CrN_{10}O_{20}S_2.3Na$	611-070-00-2	405-665-4	A mixture of: disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chloro-2-oxidophenylazo)-2-naphtholato)chromate(1-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)

Fig. 5: Extract from the Annex to Directive 2003/3/EC.

This Directive implements a new procedure for banning the use of azo dyes. Up till now, the procedure was based not on specific dyes but rather on reductive cleavage of the harmful substances (aromatic amines) generated by the dye. Annex 1 states as follows in regard to the 22 substances listed under “Number 43 – Azo colorants – List of aromatic amines:”

1. Azo dyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in the Annex, in detectable concentrations, i.e. above 30 ppm in the finished articles or in the dyed parts thereof, according to the testing method established in accordance with Article 2(a) of this Directive, may not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:
   - Clothing (...).
   - Footwear (...)
   - Textiles or leather toys (...)
2. Furthermore, the textile and leather Articles referred to in point 1 above may not be placed on the market unless they conform to the requirements set out in that point.

> By way of derogation, until 1 January 2005, this provision shall not apply to textile articles made of recycled fibres if the amines are released by residues deriving from previous dyeing of the same fibres and if the listed amines are released in concentrations below 70 ppm.

The following applies to Navy Blue (No 1 in the newly established list of azo dyes) under the new Regulation:

3. Azo dyes, which are contained in the "List of azo colorants" that is hereby added to the Annex, may not be placed on the market or used for coloring textile and leather articles as a substance or constituent of preparations in concentrations higher than 0.1 % by mass.

Since the implementation of this Directive in national law on 30 June 2004, the marketing of Navy Blue, as well as its use as a dye or as a component of dyes for textile and leather products, is prohibited in mass concentrations exceeding 0.1%.

However, this ban should not be regarded as a definitive Regulation, since item 4 of the Annex to Directive 2000/3/EC, "43. Azo colorants" states as follows:

> Not later than 11 September 2005, the Commission shall, in the light of new scientific knowledge, review the provisions on azo colorants.

d)
Risk reduction outside the purview of chemicals regulations

aa) *Industrial installation regulations pertaining to Navy Blue*

Unlike Aniline and Toluene, Navy Blue is not a volatile organic compound, which means that it is subject solely to the industrial installation regulations in IPPC and not the VOC Directive.

The use of Navy Blue is subject to the general principles governing the basic obligations of Navy Blue manufacturers pursuant to Article 3 of the IPPC Directive, insofar as the substance is used in fibre or textile dying facilities whose treatment capacity exceeds 10 tons per day (No 6.2 Annex I IPPC Directive).

bb) *Water legislation pertaining to Navy Blue*

Navy Blue has not as yet been added to the "list of priority substances in the field of water policy" in Annex X of the Water Framework Directive[115] under the "very toxic to aquatic organisms" (R 50-53) category. It is doubtful whether classifying Navy Blue as a substance that "may cause long-term adverse effects in the aquatic environment" (R 53) means that Navy Blue could be subject to the following provision of the Water Framework Directive:

> Annex VIII (INDICATIVE LIST OF THE MAIN POLLUTANTS)
>
> No. 4 "Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment"

Navy Blue is in any case subject to the following provision owing to its chrome content:

> Annex VIII INDICATIVE LIST OF THE MAIN POLLUTANTS
>
> 7. Metals and metal compounds

Thus, Navy Blue is also subject to the following point source pollution assessment and identification procedure, as stipulated by Annex II No 1.4 of the Water Framework Directive:

> 1.4 Identification of pressures
>
> Member States shall collect and maintain information on the type and magnitude of the significant anthropogenic pressures to which the surface water bodies in each river basin district are liable to be subject, in particular the following.
>
> Estimation and identification of significant point source pollution, in particular by substances listed in Annex VIII, from urban, industrial, agricultural and other installations and activities (...)

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[115] See "Decision No 2455/2001/EC of the European Parliament and the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive," OJ L 331, p. 1 – 5.

e)
Obstacles to implementation

The identification of Navy Blue poses problems, which are attributable to several factors. Firstly, a unique and readily recognizable name has yet to be defined for this substance, and even the authoritative prohibitory Directive 2003/3/EC refers to Navy Blue merely as “the blue colorant.” However, application of the New Substances Regulation has at least allowed for the definition of a unique designation, which is ELINCS no. 405-665-4 and index no. 611-070-00-2, the latter being the identification code indicated in Annex I to Directive 67/548/EC. Thus, there are now two unique, albeit numerical, designations for Navy Blue. However, these designations are not readily recognizable as, for example, a unique trade name would be, and are hence impractical for purposes of identifying the legal regulations associated with the substance.

The commonly used trade name, Navy Blue, is not a generally accepted designation, which is why it is used neither in the body nor annex of the prohibitory regulation, Directive 2003/3/EC. This has led some stakeholders to question whether this Directive even applies to “Navy Blue.” However, the indispensable precondition for efficacious substance management is for users to be able to make the connection between, on one hand, the substance itself, and on the other, the mandatory regulations in regard to the substance. In view of the complexity of the chemical compound involved here, the problem cannot be remedied by identification methods such as a molecular formula or systematic name.

The other hindrance to implementation is that since Navy Blue is a mixture of two components, it is unclear which reaction conditions (base/alkali) and ratios are applied to mixing the substance, which chromophoric compound it ultimately produces, and in which form the (heavy metal) chrome in Navy Blue occurs. The problem here is that soluble chromates can occur as either chromium(III) or chromium(VI) compounds,[116] and whereas the former are neither mutagenic, carcinogenic nor a skin irritant,[117] the latter are toxic and

[116] RÖMPP-Lexikon Chemie, (10.), 1, 738.

[117] Römpp-Lexikon Chemie, (10.), 1, 737.

sensitize the skin.[118] It could be the case that the two components form a chromophoric metal complex consisting of the two azo groups (N=N) and CrO_4^{2-} bound chromium (VI). A compound of this type contains an extended conjugated π-bonding system (see Fig. 5). The fact that such systems absorb visible light makes the attendant substances chromophoric.[119]

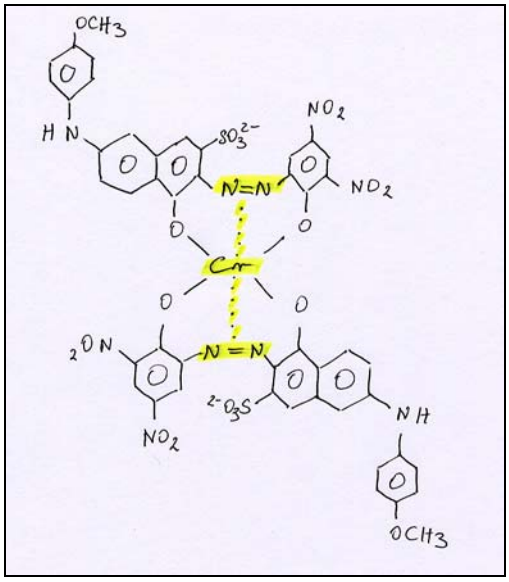

Fig. 6: Possible structural formula for the final chromophoric compound of Navy Blue.

In the case of Navy Blue, it may happen that most applications that fall within the purview of sectoral and water legislation will be realized in industrial facilities whose capacities are lower than the production thresholds defined in the Annex to the IPPC Directive. In addition, substances are likely to be discharged asynchronously and repeatedly into the water pathway. Although this problem can probably be mitigated to a great extent through suitable preventive measures such as the addition of fixing agents, the assessment of Navy Blue was unable to ascertain with certainty exactly how this solution could be implemented. Even the existence of suitable water regulations would not solve the problem, since there would still be no way to ensure compliance with monitoring procedures.

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[118] Römpp-Lexikon Chemie, (10.), 1, 738.

[119] Mortimer, p. 533.

Thus, it seems clear that for Navy Blue, obstacles exist to the establishment of an effective interface between regulatory entities at both the legislative and administrative levels, which is likely to give rise to first- and second-order instrument gaps.

4
Conclusions

The following conclusions pertaining to chemical risk reduction can be drawn from the foregoing analysis of risk reduction strategy measures and the attendant implementation mechanisms for Aniline, Toluene and Navy Blue use in the European Community:

Firstly, it is clear that even for the New Substance Navy Blue – for which data gathering, risk assessment and risk reduction is realized before the product is placed on the market – there is a sizeable information gap.

As for Aniline and Toluene, it can be safely stated that the risk assessment processes that have been realized for these substances have fallen far short of the defined goal of elaborating "tailor made" reduction mechanisms that would also result in the implementation of point-source specific solutions. Although the rapporteurs have identified highly suitable measures and have advocated the implementation of environmental quality standards and emissions limits under the IPPC Directive or Water Framework Directive, both the Existing Substances Regulation and the Technical Guidance Document on Development of Risk Reduction Strategies (TGD-RRS) lack specific provisions that would ensure that such requirements would in fact be implemented. It is obvious from the following statement that the stakeholders concerned are operating on the assumption that implementation will be an uphill struggle:

> "If the rapporteur can show that the non-implementation of EC legislation is responsible for the continued existence of risks which need to be limited, this will give the Community good reason to act."[120]

Clearly the underlying assumption here is that the industrial installation and water regulations have little chance of being implemented successfully. But if this is the

[120] TDG-RRS, p. 24, No 5.5.

case, it would seem to make little sense to use these regulations as a basis for recommending implementation measures to the Member States.

The following question also arises in this regard: Does the task of assessing and prognosticating second-order implementation deficits genuinely fall within the purview of the rapporteur? It is difficult to imagine that anything approaching an effective makeover of the problematic interface between Community chemicals regulation and other sector-specific environmental legislation can be realized under the present circumstances. The next section addresses the question of whether point source-specific legislation can serve as a basis for the resolution of the regulatory interface dilemma.

E

Implementation of risk reduction measures outside the purview of EC chemicals regulation

This section discusses (mainly in terms of the substances analyzed in the case studies above) the extent to which EC environmental law governing industrial installations and environmental media could be applied to the solution of the current regulatory interface dilemma.

The discussion begins by analyzing the proposed risk reduction strategies and concludes by considering which such strategies should be implemented for specific installation or media related regulatory interfaces. The goal here is to characterize the regulatory interface problem and formulate possible solutions to it. A summary of possible solutions to this problem can be found in section H (p. 100 ff).

1

Provisions pertaining to industrial installations

The risk reduction strategies for the case study substances, as well as other strategies such as those adopted by the Commission in 2001 and 2004,[121] make numerous references to plant-related regulations in the IPPC Directive (which are to some extent augmented by provisions in the VOC Directive). It has frequently been pointed out that emission standards should be developed (see section b) below), that environmental quality standards are needed for substances such as Toluene (see section c) below) and that suitable monitoring systems should be devised for these measures (see section E3, p. 72). However, none of this can be achieved unless the relevant risk reduction measures pertain to industrial installations that are subject to the relevant Community legislation (see section a) below)

[121] The Commission's Recommendation 2004/394/EC proposes that nine new measures be added to the IPPC Directive. The recommendations – including those pertaining to Toluene (see section D2, p. 32) – mainly concern the development of new BAT standards. Existing regulations were deemed to be sufficient for Butadine and Acrylonitrile.
Four of the measures mentioned in the Commission's risk reduction Recommendation 2001/838/EC also make reference to the IPPC Directive within whose framework a BREF document was elaborated that deals with various chemical processes.

a)
Application domain of EC industrial facility legislation

The cornerstone of EC industrial facility legislation is "Council Directive 96/61/EC concerning integrated pollution prevention and control" or the IPPC Directive, which applies to the facilities listed in Annex I of the Directive and is structured according to sector. Annex I of the Directive stipulates threshold values (production capacities or outputs) which define the scope of application. The Directive includes, e.g.,

> 6.2. Plants for the pre-treatment (operations such as washing, bleaching, mercerization) or dyeing of fibres or textiles where the treatment capacity exceeds 10 tonnes per day.
>
> 6.7. Installations for the surface treatment of substances, objects or products using organic solvents, in particular for dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning or impregnating, with a consumption capacity of more than 150 kg per hour or more than 200 tonnes per year.

Chemical plants that manufacture their products by chemical conversion are not subject to this rule. For these facilities the criterion is merely production on an "industrial scale." All industrial installations that manufacture chemicals under the REACH system are subject to the IPPC Directive. However, since Navy Blue (see case study above) is partly used in textile SMEs with a "treatment capacity" below 10 tonnes per day, insofar the use of this substance does not fall within the purview of the IPPC Directive's application domains.

The EC has other plant-related legislation apart from the IPPC Directive. First, there are regulations for specific chemicals such as the VOC Directive, which governs both the manufacture and use of Aniline and Toluene (see section D1c)aa), p. 22 and section D2c)aa), p. 29), insofar as the installation size and volume threshold criteria stipulated by this Directive (which do not match those in the IPPC Directive) are met. There are also other specific EC standards for industrial installations such as regulations governing industrial furnaces and waste treatment plants that burn fossil fuel.[122]

[122] See Führ, in: Koch/Scheuing 2003 (GK-BImSchG), Article 16 Rn. 116 et seq.

Water legislation (see section 2 below) also contains water quality provisions that apply to industrial installations. Water regulations do not specify volume thresholds of any kind, but instead apply to all industrial installations that discharge chemicals into water, whether directly (as a "direct discharger" of pollutants) or through any other means (as an "indirect discharger") via diffuse sources such as urban sewage systems, atmospheric emissions or soil contamination. Consequently, the plant-related provisions of water legislation only apply to aquatic ecotoxicity provoked by the discharge of substances such as Aniline and Navy Blue from industrial installations (see case studies above) insofar as such facilities do not fall within the purview of the IPPC Directive.

If only existing instruments are used to reduce the risk of chemical pollution from industrial installations, regulatory loopholes will exist for all chemical processes that are realized in facilities that do fall within the purview of the IPPC Directive and in which the pollution risk arises from emissions to air and soil rather than water. Although these loopholes are not relevant for the case study substances Aniline, Toluene and Navy Blue, they could arise in connection with other chemicals.

An analogous scenario can be found in German law in the "facilities not subject to permits" pursuant to Article 22 ff. of the Federal Immission Control Act (BImSchG) in Germany. Although such facilities are not subject to the stringent basic obligations defined by Article 5 of the Immission Control Act (BImSchG), the law does require that such facilities take certain minimum precautions to avoid environmental damage.[123] It would be possible at the Community level to elaborate similar requirements for facilities that do not fall within the purview of the IPPC Directive and at the same time to require these facilities to meet specific environmental quality standards in regard to emissions.

[123] See Roßnagel, in: Koch/Scheuing 2003 (GK-BImSchG), Article 22 Rn. 11 et seq.

b)
Emissions related risk reduction measures

aa) Risk reduction Recommendations

The risk reduction strategy for Toluene calls for emission reduction measures to be included in the BREF.[124] The Commissions Recommendation 394/2004 (OJ No. L 144/117) states as follows:

> It is recommended to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) that this substance is included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

On the other hand, the Commission's risk reduction Recommendation 2001/838/EC[125] states that emissions-related requirements should be "reviewed." The wording used in the recommendation is relatively vague. However there might be an underlying assumption here that new interface mechanisms between chemical and industrial installations legislation will eventually be developed since the regulation speaks in these terms ("development of new Community procedures").

The risk reduction strategies for Aniline recommend that emissions standards for this substance be defined in accordance with the IPPC Directive (BREF) or at the national level, but do not specify how this can be achieved. (see **D1d)bb)**, p. 29).

bb) *Regulatory interface problems and possible solutions to them*

The results of risk assessment reports and risk reduction strategies are "transferred" to the IPPC framework by the Commission Recommendation to consider the RRS results in the process of developing the BREFs on the best available techniques (BAT). Legally binding obligations do not result from this.

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[124] The Danish rappporteur states that "a recommendation specifying the industrial sector concerned and the attendant abatement technology should be included in the forthcoming work on the relevant BREF (IPPC)" (see section D(2)(c)).

[125] "In addition to the above, and recognising development of new Community procedures, additional measures for nonylphenol and nonylphenol ethoxylates should be considered including pollution prevention measures [IPPC-Directive] at Community level …", cf. Recommendation 2001/838/EC, OJ 2001, No. L 319/37.

However, even if the European IPPC Bureau, in the process of developing the BREFs (Article 16 IVU-RL), should follow the substance related Recommendation, no specifics are provided as to exactly how this should be accomplished. The same holds true for the time frame that has to be assumed for elaboration of the various (new) BREFs. Moreover, the compilation of best available techniques within the BREFs should not be confused with mandatory Community-wide emissions control limits. This can only be accomplished by implementing mandatory obligations for the operators of the relevant industrial installations,[126] which is usually realized by adding specific clauses to the permits of such facilities. In so doing, the competent authorities of the member staters have to consider the contents of the BREFs, although they do not define the clauses of the permit.[127]

BAT-oriented recommendations pertaining to chemicals legislation constitute “potential risk reduction measures” that are realized within the framework of risk reduction strategies and are evaluated in light of their *effectiveness* and *proportionality*. Such measures often involve emission reductions in production and processing as well as in connection with downstream uses (manufacturing and processing) of a given chemical, which in some cases occur in facilities that fall within the purview of the IPPC Directive.[128] Moreover, if PNEC immission levels are exceeded, risk reduction strategies can also entail what are in some cases extensive efforts to find technical solutions that could reduce the emissions[129] of a given substance and

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[126] The integration of recommendations into adminstrative rules such as TA Luft (German technical instructions pertaining to air quality control) do not establish binding regulations for operators, but this could be accomplished by means of government regulations (see the section pertaining to implementation of the VOC Directive in 31. BImSchV).

[127] See Article 9(4) of the IPPC Directive which stipulates that the technical characteristics of the installation must be taken into account (among other things). The Appendix to Article 3(6) of the German Immission Control Act (BImSchG) No 12 states that the contents of BREFs must be taken into account (see Jarass, commentary (in German) on BImSchG, 5. Ed, 2002, Article 3, Rn. 92 et seq.)

[128] See for example section 4 of the toluene risk reduction strategy.

[129] The term “emissions” should be understood in its broadest sense as defined by the IPPC Directive. The term means (as defined in Article 3(6) of the German Immission Control Act (BImSchG) and unlike the definition of emissions in Article 3(3) of the same law) emissions to any environmental media. This definition is analgous to the

mitigate the resulting economic impact. The criteria defined by chemicals regulations for the selection of risk reduction measures (effectiveness, practicality, economic impact, monitorability)[130] provide for the evaluation of different alternatives. Thus, the process of elaborating risk reduction strategies inevitably has an impact on the regulatory domain of plant-related legislation.

Nonetheless, the differing goals of chemical risk reduction versus plant-related regulations should be borne in mind. The primary aim of chemicals regulations is to minimize the risk associated with individual chemicals, whereas the IPPC Directive strives for “integrated pollution prevention” in regard to all adverse environmental effects that could be provoked by a specific production facility. These divergent approaches could ultimately provoke a de-prioritization of emissions reduction goals for individual chemicals since an

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environmental media-oriented approach taken by the Water Framework Directive. The goal of the permits that are granted by the competent national authorities under the IPPC Directive is to achieve a “high level of protection for the environment as a whole” in an integrative manner (see sections 1(2), 3(6), and 5(1) of the German Immission Control Act (BImSchG)).

[130] See TGD-RSS (“Step 4”), 23 et seq.

integrative approach that weighs competing reduction goals will tend to reshuffle priorities to the detriment of substance-specific objectives. From a substance law perspective, this would not be a satisfactory solution. Nevertheless, Article 3(b) of the IPPC Directive requires that industrial installations be operated in such a way that "no significant pollution is caused." Article 3(a) of the IPPC Directive stipulates that "all the appropriate preventive measures [should be] taken against pollution, in particular through application of the best available techniques,"[131] which constitutes a de facto supplementary immissions regulation (see section E1c) p. 63). The fundamentally different objectives of chemical and plant-related regulations (see section H2b), p. 105) would constitute a far less insurmountable hindrance to regulatory compliance if an effective immissions-related interface were established between them. The implementation of suitable monitoring mechanisms would also ensure that regulations were enforced at industrial installations.

cc) *Conclusions*

The interface between the Existing Substances Regulation and IPPC Directive has yet to be harmonized at the legislative level. This can be said to constitute a first-order interface gap. Experience to date appears to indicate that for numerous chemicals this situation will ultimately lead to an implementation deficit at the administrative level and thus a second-order implementation deficit – induced by the the first-order interface gap – is likely to occur.

The fact that the criteria for the control of existing chemicals (effectiveness, practicality, economic impact, monitorability) essentially reiterate the criteria of the principle of proportionality (which is a general principle within Community law[132]) would appear to indicate that the results of chemical risk assessment and reduction procedures could be usefully applied to plant-related regulations if the competent Member State authorities drew upon these results by analogy, as long as the relevant BREFs are not adopted.

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[131] Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control

[132] Cf. Krämer, EC Environmental Law, 5th. Ed., 2003, 3-06 et seq. and 3-50.

However, this would mean that chemicals regulations would have to define which aspects of risk reduction strategies the aforementioned process should be applied to, and the reverse would have to be stipulated in the IPPC Directive, perhaps as an amendment to Article 16 (2) that would state as follows: “Information exchange in this Directive also encompasses the relevant constituents of risk reduction strategies as defined in Article 10(3) (2)of Directive 793/93 EC.” As stated above (section bb)), a provision of this nature would not be legally binding for the Member States, although they would be required to take into consideration the results of evaluations pertaining to chemicals regulations when determining permit conditions for industrial installations.

c)
Immission related risk reduction measures

aa) *Risk reduction Recommendations*

The Commission’s 2004 risk reduction Recommendations repeatedly state the following:

> “Local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.” [133]

This statement – although implicitly (“no risk for the environment“) - indicates that immissions should not exceed the no-effect threshold.

At the same time the broad definition of emissions in Community law (see Article 2 No 5 of the IPPC Directive) encompasses all types of environmental impact, resulting as well in some overlap with water legislation (see section E2, p. 65).

bb) *Regulatory interface problems and possible solutions to them*

The Existing Substances Regulation follows an effect- and immisson related approach (see section C1b, p. 11). The need for risk reduction is constituted by any exceedance of the PNEC. However, in the absence of a nexus between regulations

[133] Risk reduction Recommendation 2004/394/EC, OJ No. L 144, p. 79, 88 f., 93, 101, 105, 112 and 117 (toluene).

governing industrial installations and chemicals regulations, the provisions of the Existing Substances Regulation cannot be effectively implemented. The resulting implementation deficit is attributable to an instrument gap (in the form of a lack of regulatory interfaces) at the legislative level.

One possible solution to this dilemma – offering a high level of legal certainty – would be to adopt Community environmental quality standards as a daughter directive to the Air Quality Framework Directive. However, in view of the large numbers of Existing Substances that have to be regulated and the (in many instances) few problematic point sources involved, this solution would probably be workable in exceptional cases only. Therefore, a solution should be sought (one not currently embodied in Community law) whose political and administrative transaction costs are low and that would be provision within Community legislation stating the assumption that the PNECs define the environmental injury level (see section H2b), p. 105).

This should be done for the primarily pragmatic reason that the threshold values defined in the PNEC – and elaborated pursuant to standardized Community-wide procedures with the participation of all competent Member State authorities as well as the scientific committee – constitute a plausible basis for risk assessment. However, the validity of the PNECs cannot overcome inevitable scientific uncertainties, and the absence of a formal enacting resolution robs them of the legal gravitas[134] that would prompt the competent national authorities to enforce these parameters strictly.

cc) *Conclusions*

In terms of resolving the regulatory interface problem, it would be useful to impose the following obligations on the

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[134] The Directive explictly states (in Article 10(3)(1)) that risk assessment falls within the purview of the rapporteur. However it seems doubtful whether adopting “the results of the risk evaluation” and the “recommended strategy” via committee procedures (Article 11(2) in combination with Article 15 of Council Regulation (EEC) No 793/93; see also section **C1c)**, p. 13 herein) would carry the same weight as formally adopting PNEC parameters. However, this uncertainty could be resolved by clearly defining the relevant regulatory interfaces and adopting the PNEC parameters as Community law. It would of course then be necessary to define the legal ramifications of this measure for the implementation of other sectoral regulations.

competent authorities (in accordance with the relevant proposed solutions discussed herein (see section H, p. 100)) in regard to point sources that have been found to be problematic during the substance assessment process:

- Explicit obligation to measure immissions levels
- Obligation to investigate and validate possible risk reduction measures
- Obligation to file reports explaining the actions taken

Suitable monitoring mechanisms would also have to be established (see section E3, p. 72).

2

Water legislation

Community water legislation is currently in a transitional phase. In addition to the Water Framework Directive and its "ecosystem" instruments, existing Directives will also remain in force for a time[135] and thus will continue to form the legal framework for the Commission's risk reduction recommendations. The Commission has recommended that the "list of priority substances" be augmented in accordance with Annex X of the Water Framework Directive (see section a) below) and that interim measures be adopted pursuant to Directive 76/464/EC(b). The Commission has also recommended that dangerous Existing Substances be classified as harmful in accordance with Annex VIII No 4 of the Water Framework Directive (see section c) below)[136] and that these substances be taken into consideration when surface water status classifications are formulated (see section d) below).

In the following, the various legal instruments proposed by the Commission in its Recommendations are described along with the consequent regulatory interface problems (section aa)). Possible solutions to these problems are then discussed (section bb)).

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[135] See Seidel/Rechenberg 2004, 213 et seq.

[136] Regulatory nexuses would also have to be identified in waste management and soil protection regulations for the water treatment residues of substances that have caused problems in the past (e.g. the case study substances discussed above).

a)
Inclusion in the "List of priority substances" (Annex X, Water Framework Directive)

Aniline and Toluene have not yet been added to the "list of priority substances in the field of water" in Annex X of the Water Framework Directive.

aa) *Risk reduction Recommendations*

It is possible that Existing Substances that pose a threat to the aquatic environment will eventually be added to the list of priority substances, as was recommended in the risk reduction strategy for Toluene (see 2004/394/EC, point D(2)(c)).

Article 16(2) of the Water Framework Directive defines a selection procedure for the list of priority substances that explicitly refers to the procedure defined in the Existing Substances Regulation.[137] The Water Framework Directive narrows this cross-regulatory brigde by stating – in accordance with the principles of subsidiarity and proportionality – that substances are only to be included insofar as they pose a threat of "widespread environmental contamination" (Water Framework Directive, Article 16 (2)(2)(3). If this is the case, Community-wide risk reduction strategies for surface water should be applied.

bb) *Conclusions*

Although there is a regulatory interface between Existing Substances and water legislation for the priority substances listed in Annex X, it remains to be seen whether the competent authorities will apply the relevant substance related Recommendations, which are not mandatory. Adding a legal obligation in this regard would probably not accomplish a great deal in view of the fact that Annex X priority substances are – for comprehensible reasons – to be

[137] However, the Regulation allows for a simplified risk assessment procedure based on scientific principles. Known as Combined Monitoring and Modelling Priorisation of Substances (COMMPS), this is the first instrument to apply multiple assessment methods concurrently and on an equal footing. Priority substance status is determined on the basis of this procedure (2455/2001/EC of 15 December 2001, EC-OJ L 331/1), a stipulation which can also be inferred from the sixth recital of the Water Framework Directive.

selected on the basis of surface water criteria and the need for action in their regard.

The elaboration of water risk reduction strategies for priority substances falls within the jurisdiction of the Commission. The Commission's recommended strategies must meet the same criteria (effectiveness, practicality, economic impact, and monitorability) that apply to risk reduction strategies according to the Existing Substances Regime (see Article 16(6) of the Water Framework Directive). It therefore follows that risk assessment findings should be applied not only (as has hitherto been the case) to the selection of priority substances but also to the emissions reduction measures that are carried out on the basis of these findings.

However, no procedure currently exists for point source emissions posing a risk that are not (yet) included in the Annex X list of priority substances. Thus a mechanism that would harmonize these two regulatory frameworks is lacking.

Recapitulating, this is also likely to lead to a legislative instrument gap between the Existing Substances Regulation and Water Framework Directive. Consequently, the competent authorities may fail to implement emissions reduction measures that are regarded as necessary at the Community level under the Existing Substances Regulation.

b)
Interim strategy based on Directive 76/464/EC

Inasmuch as definition of a new Annex X priority substance list has already taken some time and will in any case not be realized definitively until agreement has been reached on the relevant Community-wide measures,[138] the question arises as to whether an interim strategy should be implemented.

[138] Article 16(8) of the Water Framework Directive, which also stipulates (sentence 3) that in the absence of an agreement at Community level, the Member States will implement the relevant measures five years after a substance is added to the list.

aa)
Risk reduction Recommendations

The risk reduction recommendations stipulate that the water quality provisions of Council Directive 76/464/EC, which expires in 2013, should apply:

> "(...) [I]n 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"[139]

The Directive also calls for the implementation of national quality objectives, a monitoring system[140] and, where appropriate, emissions reduction measures.

bb) *Conclusions*

In light of this situation, the role that should or could be played by the standards (PNECs) in the Existing Substances Regulation and by the pollution scenario expertise that has been acquired should be clearly defined (see sections E1c)bb), p. 63 and H2, p. 103). Currently the regulations or administrative standards that would allow for elaboration of the relevant regulatory interface are lacking.

c)
Dangerous substances listed in Annex VIII No 4

The case studies of Aniline, Toluene and Navy Blue show that some problematic point sources occur in a manageably small number of Member States only. Thus, as previously mentioned, it would not make much sense to (once again) attempt to hammer out the kind of elaborate Community-wide regulatory harmonization process that is called for in the Water Framework Directive. Instead, solutions for specific point sources should be sought.

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[139] Risk reduction Recommendation 2004, OJ No L 144/117.

[140] If this only pertains to a limited number of point sources, it would make little sense to institute comprehensive monitoring (although the Directive does not explictly call for this either).

However, the question then arises as to whether the Water Framework Directive is a suitable tool for this kind of decentralized problem solving. The “Indicative list of the main pollutants” in Annex VIII of the Water Framework Directive might be a good starting point for dedicated point source solutions, since in addition to listing substances and substance groups it also specifies parameters such as qualitative criteria (in No 4).

aa)
Risk reduction Recommendations

Among the substances discussed in the case studies herein, Toluene[141] definitely falls within the purview of Annex VIII No 4 of the Water Framework Directive by virtue of its classification as an R 63 substance (“Possible risk of harm to the unborn child”).[142]

This means that, pursuant to Article 5 and Annex II of the Water Framework Directive, Member States are required to estimate and identify significant point source pollution:

> Annex II, No 1.4: Estimation and identification of point source pollution
>
> “Estimation and identification of significant point source pollution,[143] in particular by substances listed in Annex VIII, from urban, industrial, agricultural and other installations and activities (...)”

The Member States are required to base their risk reduction programs on this estimation and identification procedure. In this regard, Article 11 paragraph 3(g) of the Water Framework Directive calls for limits on point source emissions in accordance with Articles 10 and 16 of the Water Framework Directive.

Article 15 of the Water Framework Directive obligates the Member States to submit reports (albeit in summary form) regarding their environmental management programs in accordance with the analyses specified in Article 5 and the

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[141] As pointed out above (p. 22), Aniline is a substance of concern because it may cause cancer in humans.

[142] This may also apply to Navy Blue if the usage restriction on this substance is rescinded.

[143] Diffuse sources are subject to the same requirement.

monitoring program specified in Article 8 of the Water Framework Directive.

bb) *Conclusions*

The legal instruments alluded to above appear to be suitable solutions (in light of the conclusions formulated in section E1c)cc), p. 64 as well) for the regulatory interface problem in regard to water protection. However, two caveats apply here: First, not all substances for which point-source related measures appear to be required pursuant to the stipulations of the relevant risk reduction strategy meet the Annex VIII criteria. Second, there is currently no Community coordination procedure for the Annex VIII substance classifications.

Thus, further clarification is needed for substances that do not fall within the purview of Annex VIII. In addition, a transfer mechanism should be devised that establishes an interface between the chemicals regulations on one hand, and substances that fall within the purview of Annex VIII of the Water Framework Directive on the other. This could be done by simply stating in the risk reduction strategy that the substance in question meets the criteria of Annex VIII. In addition, for practical reasons an "Annex VIII No 4 substances" list should be established for and made readily available to the competent Member State authorities implementing the water related legislation. Also needed is a mechanism that ensures that risk reduction strategy information regarding problem point sources reaches the competent authorities in the relevant Member States.

d)
Monitoring of water status

Risk reduction measures primarily aim to reduce substance emissions. But water status must also be monitored (see section E3, p. 72). Article 2(17 ff) of the Water Framework Directive contains definitions for the characterization of water status[144] and requires the Member States (in Article 4

[144] Recital No 25 of the Water Framework Directive states as follows: "Common definitions of the status of water in terms of quality and, where relevant for the purpose of the environmental protection, quantity should be established. Environmental objectives should be set to ensure that good status of surface water and groundwater is

of the Water Framework Directive and elsewhere) to strive for “good water status” at a minimum.[145]

“Monitoring of ecological status and chemical status for surface waters” (Annex V(1.3) of the Water Framework Directive) could be a starting point for the emissions reduction for Existing Substances. According to Annex 5 of the Water Framework Directive, the “quality elements for the classification of ecological status” (1.1) include the “chemical and physico-chemical elements supporting the biological elements” (1.1.1). The “specific pollutants” category (and rubric) encompasses both “pollution by all priority substances identified as being discharged into the body of water” as well as “pollution by other substances

achieved throughout the Community and that deterioration in the status of waters is prevented at Community level.”

[145] Recital No 26 of the Water Framework Directive states as follows: “Member States should aim to achieve the objective of at least good water status by defining and implementing the necessary measures within integrated programmes of measures, taking into account existing Community requirements. Where good water status already exists, it should be maintained. For groundwater, in addition to the requirements of good status, any significant and sustained upward trend in the concentration of any pollutant should be identified and reversed.”

identified as being discharged in significant quantities into the body of water."

The competent authorities in the relevant Member States would also be enabled to investigate such "other substances" using the information gathered in connection with risk management processes.[146] The Water Framework Directive also requires the competent authorities to monitor these pollutants insofar as they occur locally in "significant amounts." This would necessitate information transfer from the REACH-related risk reduction and risk management processes to the local water authorities.

3
Implementation, monitoring and information exchange

The most reliable test of the suitability of a risk reduction strategy is its successful implementation. A suitable monitoring system should verify whether the potential for pollution reduction has been successfully leveraged, and the extent to which risk reduction recommendations have been implemented.

a)
Risk reduction Recommendations

The risk reduction Recommendations pertain to implementation by individual Member States, as well as point source monitoring:[147]

> "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 (...) [L]ocal emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected."

The Recommendation requires the Member States to realize a number of tasks. For instance, it asks to implement the best available technologies stipulated by specific installation

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[146] Annex V(1.3.2) stipulates that "quality elements" should be selected for the "design of operational monitoring," which should be carried out for "all priority substances discharged, and other pollutants discharged in significant quantities."

[147] Risk reduction Recommendation 2004/394/EC, OJ No 144, p. 79, 88 f., 93, 101, 105, 112 and 117 (toluene).

permissions, insofar as such technologies have been defined clearly enough and have been incorporated into the relevant scenario of the industrial installation regulations (see section E1b)bb), p. 59).

Article 16 of the IPPC Directive defines a regulatory and procedural framework at the Community level for the mandated exchange of information regarding the best available technologies (BAT). However, no regulatory framework is defined for the local monitoring of Existing Substances emissions. Community risk reduction strategies and emissions monitoring are linked only insofar as the competent authorities of the relevant Member States have to follow rules governing the relevant point sources either into plant-related or water regulations (see section E1, p. 56 ff.) for specific Existing Substances (see, for example, Article 14 of the IPPC Directive). However, the manner in which Member States currently report substance-related information to Community institutions is problematic. First, only a limited number of substances are reported, and second, the Member States report mean figures in lieu of specific individual or even maximum figures. It is therefore impossible to determine whether this procedure has allowed to control the outcome of the implementation of risk reduction measures for point source emissions in any specific instance.

In addition, neither the emissions of IPPC installations for which no emissions limits have been defined for dangerous Existing Substances, nor the emissions of non-IPPC installations can be systematically monitored.

Immissions monitoring is required under water legislation whenever such monitoring is a permit condition of an IPPC installation and the competent authorities actually realize such monitoring (see Article 14 indent 1 of the IPPC Directive) or in the cases where the water status is monitored according to the provisions of the Water Framework Directive (see section E2d), p. 38).

b)
Regulatory interface problems and possible solutions to them

On the basis of the sectoral Community law it is readily possible (though not explicitly ensured) to implement the emission related recommendations defined by risk reduction strategies (under the conditions described in section E1b)bb), p. 59). Nevertheless, no instruments have yet been

elaborated that would enable compliance monitoring for the reduction of Existing Substances emissions. In keeping with the objective of chemicals legislation, which is to systematically reduce the risk occasioned by Existing Substances, monitoring tools should be suitable for both known point sources as well as other existing or new emissions sources.

Toward this end, a series of emissions monitoring tools known as EPER (European Pollutant Emission Register) can be used, some of which are currently available and others of which are under development. EPER stipulates that emissions to air and water from large industrial installations should be reported to the European Commission. Some substances from the Existing Substances Regulation are already covered by the EPER system (albeit only to a limited extent)[148]. A more comprehensive system known as PRTR (Pollutant Release and Transfer Register) – which, as its name suggests, also encompasses pollutant transfer that exceeds the scope of emissions – is slated to be operational by 2009.[149]

Neither smaller point sources nor diffuse emissions fall within the purview of either system, however. In any case, for those sectors that risk reduction strategies have identified as exceeding PNEC limits, an *immission* monitoring system is needed (which could be readily implemented using currently available instruments) as well as a Community-wide coordinated reporting system. No legislation regarding pollution from Existing Substances currently provides for such measures.

c)
Conclusions

In the interest of achieving more comprehensive emissions monitoring, Existing Substances that require monitoring pursuant to the relevant risk reduction strategy should fall within the review mechanisms of the EPER and PRTR systems (see section H2d) p. 109).

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[148] For more information on EPER (including data from 2003) see http://www.eper.cec.eu.int/.

[149] This system is based on the PRTR protocol, which was adopted on 21 May 2003 as part of the Aarhus Convention at the Fourth Ministerial Conference in the "Environment for Europe" process under the aegis of the UN Economic Commission for Europe (UNECE) (see http://www.eper.cec.eu.int/eper/SupportingDocuments.asp).

An additional useful objective would be to establish an immissions monitoring system that is based on specific (potential) pollution scenarios, along with a suitable Community-wide reporting mechanism.

4

Recapitulation

Our conclusions regarding the implementation of risk reduction strategies for Existing Substances that exceed the scope of / are not covered by Community wide marketing and use restrictions can be summarized as follows:

1. These strategies and recommendations:

   (i) are amenable to medium-term implementation.

   (ii) require cooperation of the competent authorities of the relevant Member States for which (a) there is no generally applicable regulatory framework beyond that provided by (non-binding) Commission recommendations; (b) there are no discrete regulatory interfaces except sporadic links found in water legislation; and (c) no established administrative mechanisms exist.

2. Effective monitoring mechanisms at Community level have yet to be established and the absence of such mechanisms makes it impossible to determine whether risk reduction strategies have been successfully implemented and whether further action is needed.

We have uncovered regulatory deficits at the legislative level for all interfaces investigated. Legal mechanisms securing that needed and suitable emissions reduction measures which have been identified within the framework of the Existing Substances Regulation are lacking. Indeed, if past experience is any guide, it is highly unlikely that such measures will be implemented at any time in the near future.

The possible solutions for this problem were discussed above in connection with the relevant regulatory interface problems. Proposals for implementation of these solutions will be recapitulated in section H, likewise in their relevant contexts.

F Reduction of Existing Substances emissions under REACH

The REACH regulatory framework constitutes a new approach on the part of the Community to institute a substance related[150] risk management strategy that enlarges the scope of current legislation. Crucial points of the new chemical policy are the integration of New and Existing Chemicals within a harmonized legal framework and the shift of responsibility for a safe use towards industry (REACH Article 5 ff.).

The REACH regulation defines much more extensive obligations for manufacturers and importers of Existing Substances relative to current chemicals regulations while keeping a “safety net” for mandatory regulations. However, REACH is much weakened compared to earlier drafts of the Regulation and is greatly in need of more specific environmental protection standards (SRU Umweltgutachten 2004, Tz. 992 ff. and 1033 ff.).

In terms of the regulatory interface problem, the following passage in the proposed REACH regulation under the heading “Coherence with other policies” is noteworthy:

> "Chemicals policy interfaces with a wide range of other policy sectors. In preparing its proposal, the Commission has been careful to avoid duplication of the provisions of other legislation, while not creating loopholes and ensuring that necessary information is made available to other sectors."

In the following, the extent to which REACH resolves the regulatory interface dilemma is discussed. The first section focuses on manufacturers and importers, while section 2 addresses the legislative and administrative dimension of the problem.

1 Obligations of manufacturers and importers

Manufacturers and importers that manufacture/import volumes totaling one ton or more are subject to a registration system that requires them to submit a (relatively thin)

[150] The term “substance” in connection with REACH does not refer solely to the narrow definition of “substance” in accordance with Community chemicals legislation (see Article 3(1) of REACH), but instead also encompasses “preparations” and “products” (see the definitions in Article 3(2) and 3(3) No 2 of REACH as well as the obligations and limitations defined in Articles 5f., 64 and 65 of REACH).

technical dossier containing information on the relevant substance properties and risk management measures, as well as – starting at 10 tons – a chemical safety report that explains which specific measures are appropriate. Substances "of particular concern," are subject to an authorization system (REACH, 13 ff.; SRU Umweltgutachten 2004 section 991 ff.). Authorization conditions and the general restrictions therein must also be adhered to.

The scope and application domain of the basic obligations of the substance stewards[151] are highly relevant to the regulatory interface problem.

a)
Basic obligations

The basic obligations of manufacturers and importers for substances that are subject to registration are defined in Article 13 of REACH, "Chemical safety report and duty to apply and recommend risk reduction measures."

> "Any manufacturer or importer shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 29."

The (rather infelicitous) wording here appears to indicate that there is *a basic obligation to assess and limit risk*, similar to that defined in Article 6(1) and 6(2) of the German Gene Technology Act (GenTG). The provision pertains to manufacturers and importers, who can also be thought of as "substance stewards."

The REACH regulation requires substance stewards to compile substance data and apply suitable "risk management measures"[152] To the intended uses. The self responsibility

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[151] The terms "substance stewardship" and "substance steward" are used in this text to point out the new quality of non governmental responsibility that plays a vital role in the REACH approach to environmental protection. Manufacturers and importers will have to take comprehensive private responsibility for substances and a safe use during life cycle.

[152] The purpose and legal significance of these measures remain somewhat opaque in the REACH recitals. A conservative reading of the recitals could suggest that a limitation on the scope of substance safety assessments is being defined. However, the wording of the regulation appears to mean that manufacturers and importers have a separate legal obligation, a concept that is often found in product

pertains in particular to situations where risks are controllable and general restrictions on marketing and use would be improper.

This is a scenario that can be described as the legal attribution of personal responsibility.[153]

Here the basic obligation to reduce risk also requires “downstream users” to exercise a safe use, which also pertains to actions whose application domains fall within the purview of industrial installation and water legislation. Since REACH does not define the relationship between industry’s substance related basic obligations and its obligations in the realm of sectoral environmental law,

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law. For example sections 8, 24 and 30 of the German Food and Consumer Products Act (Lebensmittel- und Bedarfsgegenständegesetz) contain general prohibitions whose purpose is to safeguard human health. The obligations defined in Article 13(6) of REACH adopt an analogous approach, integrating human health and environmental protection. However, here the upstream phases of safety management in the product chain are targeted with a view to operationalize the general ban on the marketing of hazardous products.

[153] For example, SRU Umweltgutachten 2004, item 755. For a general overview of the concept of personal legal responsibility, see Führ 2003. For a discussion of (past) chemicals laws, see Führ 2000b.

it is safe to assume that both types of obligations are applied concurrently (obligation to intervene). The limitations of regulatory measures stipulated by REACH in connection with the authorization procedure (see Article 57(2) of REACH and section F2b), p. 84) do not appear in Article 13 of REACH. This makes sense, however, since substance stewards' obligations are defined comprehensively, these obligations do not address the issue as to whether a specific substance also falls within the purview of any of the other numerous sectoral regulations.[154] On the other hand, Community authorization decisions should of course not overlap with plant- and water legislation-related decisions made by the competent authorities of the Member States (for a critique in this regard, see SRU Umweltgutachten 2004, No. 1032).

Substance stewards' obligations pertain to single substances and are defined comprehensively in this regard, irrespective of the manner in which the substance is used or the exposure scenarios within which the substance has an environmental or health impact.[155]

b)
Compliance with restrictions

In addition to the obligations of substance stewards stipulated by REACH, the regulation also grants the competent authorities the power to undertake restrictions on marketing and use. Article 64(1) and 64(2) of REACH require substance stewards to comply with Community substance restrictions:

> A substance on its own, in a preparation or in an article, for which Annex XVI [and, as per paragraph 2, Annex XVII] contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction.

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[154] Exceptions occur only insofar as a dedicated substance regulation exists (see Articles 4 and 13(2) of REACH).

[155] If this basic obligation is to successfully motivate substance stewards to take action that will support implementation of REACH objectives, an institutional "framework" should be elaborated that promotes fulfillment of this obligation at the lowest possible transaction cost (Führ 2003). As for Existing Substances, it should be ensured that "traditional" manufacturing, marketing and usage behaviors are "deconstructed," which will entail "conversion costs."

c)
Obligations of substance stewards

In the view of the present authors, REACH promulgates (a) general substance stewards' obligations in regard to chemical substances, such obligations being unrelated to specific Community instruments in this regard and (b) specific restrictions that Community institutions are authorized to impose on substance stewards, who are required to comply with them.

The overarching legal principle is that the primary responsibility for the identification and management of chemical risk lies with industry. This means that industry is required to "assume sole responsibility for risk management" throughout the product chain.[156] Substance restrictions imposed by Community measures are of a supplementary nature and are meant to provide a "safety net to manage risks that have not been adequately addressed by another part of the REACH system." (REACH, p. 12).

Substance stewards' obligations also extend to other spheres of Community environmental legislation. The absence of a preference rule in REACH means, in terms of environmental law, that each stakeholder is responsible for complying with the regulations one by one to which he is subject. For the stakeholders concerned, this can be a daunting administrative task that engenders high transaction costs. It therefore behooves all actors, including the regulatory institutions concerned, to find ways to minimize these costs.[157]

2
Official cognizances

The competent authorities (which in this case means the executive institutions of the Member States in conjunction with the European Commission, the European Chemicals Agency

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[156] Holleben/Schmidt 2002, 538. On the subject of substance related self-responsibility of companies, see Führ 2000b; see Führ 2003 on the legal basis and instruments for the regulation of industry actions under the "self-responsibility" model.

[157] Some approaches in this regard – based on the behavioral model of "homo oeconomicus institutionalis" and "institutional man" (Bizer 1998 and 2002, Führ 2003) – include the "visibility" of the requirements of various regulatory frameworks, standardized guidance with the work involved, and the initiation and furtherance of cooperation.

and the two Committees) have to evaluate the registrations that are submitted, to determine which substances are subject to authorization and to issue authorizations. In the future, regulatory committees will be authorized to define general restrictions, which constitute the most far reaching regulatory measures.[158]

In the following – in keeping with the primarily administrative and legislative orientation of the Existing Substances regime – the spheres of action of the competent authorities are described in terms of the restrictions, the authorizations and evaluation of data.

a)
General restrictions

The provisions of Articles 64-70 of REACH form the basis for the implementation of general risk reduction measures.

Article 64 of REACH stipulates that substance stewards' activities in manufacturing, marketing and use of substances must comply with Community restrictions. The procedure for "introducing new and amending current restrictions" is described as follows in Article 65(1) of REACH:

> When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVI shall be amended in accordance with the procedure referred to in Article 130(3) by adopting new restrictions, or amending current restrictions in Annex XVI, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 66 to 70.

Annex XVI of REACH retains the current restrictions pursuant to Directive 76/769. This forms the basis for the REACH instruments that will allow current restrictions to remain in place, under specific conditions which shall now be discussed.

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[158] Such decisions have thus far been made by committees composed of members of parliament and the ministerial council.

aa)
Scope of possible restrictions

Directive 76/769[159] merely defines "restrictions on placing on the market and use"[160] (Article 1).

Article 65 of REACH, on the other hand, calls for "restrictions on the *manufacture*, use or placing on the market"[161] but only insofar as the risk "needs to be addressed on a Community-wide basis." However, the exact meaning of "restrictions on the manufacture" needs clarification, as does the significance of the precondition that a Community-wide regulation is needed ("an unacceptable risk[162]...which needs to be addressed on a Community-wide basis.")

The risk reduction "instrument gap" that lies outside the purview of use restrictions and labeling rules could perhaps be reduced if regulations for specific manufacturing processes could be elaborated on this basis.

bb)
The meaning of "restriction on manufacturing"

The REACH regulation does not specify what is meant by "restriction on manufacturing." Does it mean only a ban on production? Or does this stipulation also allow for the elaboration of detailed rules regarding manufacturing processes, e.g. safety or emissions requirements that would reduce the associated risk?

The specific explanations in Articles 64 ff. provide no indication whatsoever as to the meaning of this phrase (REACH 127 ff.). However, the introduction to the Commission's proposal states as follows (REACH, 16):

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[159] This Directive defines restrictions – without prejudice to other applicable Community regulations – on the marketing and use in the EU of the dangerous substances listed in the Annex.

[160] The manufacturing restrictions that have been imposed on this basis constitute "uses" for the manufacture of *other* products. For instance the use of hexachlorethane (CAS No 67-72-1, EINECS No 200-666-4) is prohibited for the manufacture or processing of non-ferrous metals (REACH, Annex XVI No 41).

[161] Emphasis added.

[162] The question as to what constitutes an "unacceptable risk" and the related question as to the intervention threshold for Community restrictions are of central importance for REACH implementation (SRU Umweltgutachten 2004, No 1033 et seq.)

> Proposals for restrictions may consist of conditions for the manufacture, use(s) and/or placing on the market of a substance or of the prohibition of these activities if necessary.

It follows from this that REACH will also allow for the regulation of specific *manufacturing conditions* for all substances that fall within the purview of the system. However, the restrictions defined in Annex XVI pertain to marketing and use only, which is due to the fact that these restrictions were enacted on the basis of current regulations, whose scope is narrower than those in REACH.

If this is the case, chemical and plant-related regulations can be said to overlap[163] at the legislative level, where overlaps in the scope of legal instruments are common and where general regulations pertaining to substance use can give rise to scenarios that clearly necessitate intervention (lex specialis derogat lex generalis).[164]

cc)
Need for Community-wide risk reduction

Article 65 of REACH stipulates that a risk must "[need] to be addressed on a Community-wide basis." This proviso can be regarded as an instance of second-order legal implementation of the primary-law subsidiarity principle promulgated in Article 6(2) EC, which states that in areas that do not fall within the exclusive competence of the Community (such as customs and agriculture), the Community shall take action "only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community."

Existing Community instruments contain provisions pertaining to specific processes, primarily in the realm of air quality (e.g. in regard to industrial furnaces and waste incineration plants), as well as hazardous substance regulations pertaining to installations that generate

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[163] Chemical manufacturing plants fall within the purview of Annex I No 4 of the IPPC Directive.

[164] Regarding this problem and the misguided attempt on the part of the Federal Constitutional Court (Bundesverfassungsgericht) to demonstrate that the German Constitution supports the concept of "regulatory consistency," see Führ 1998.

volatile organic emissions (VOC Directive, see sections D1c)aa) and D2c)aa)).

But regulations beyond this are few and far between, apart from those governing waste that is "removed" via the air pathway. Worthy of mention in this regard is the Directive regarding waste generated by titanium dioxide production, which was enacted in response to protests against "dumping" industrial acid waste on the high seas.

dd)
Conclusions

Under these preconditions, it would seem that any high-risk production process would potentially be subject to restriction or even prohibition. However, any such regulation would take precedence as lex specialis over the relevant sectoral legislation as it would constitute a specific substance regulation. This solution would not provoke any regulatory interface problems, nor is there any evidence that the provisions of REACH would rule out the implementation of this instrument on legal grounds.

However, obstacles might rather occur in the political and administrative arena. In view of the considerable expense and effort that elaboration and adoption of this kind of restriction would entail – particularly since it deals with specific aspects of current manufacturing practices as well as the ambiguity of material authorization requirements – it is highly unlikely that such an instrument would be used to any significant extent.[165]

b)
Authorization requirements

REACH requires that authorizations be issued, on the basis of a prescribed procedure, for Existing Substances that are found to be of "particular concern" ((REACH 16 and 34 ff., Article 43a ff.).

Chapter 2 (Article 57 ff.) on the granting of authorizations defines specific rules pertaining to the regulatory

[165] In its 2004 environmental report (SRU Umweltgutachten 2004, No 1064 column 3) the German Advisory Council on the Environmental (SRU) concurred with this view, noting that restrictions are likely to be imposed in the future in "open and shut cases only."

interface problem. Article 57(1) states as follows in this regard:

> "An authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII is adequately controlled in accordance with Annex I, section 6, and as documented in the applicant's chemical safety report."

Paragraph 2 states as follows:

> The Commission shall not consider the following:
>
> – risks to human health and the environment of emissions of the substance from an installation for which a permit was granted in accordance with Council Directive 96/61/EC49;
> – risks to and via the aquatic environment of discharges of the substance from a point source governed by the requirement for prior regulation referred to in Article 11 (3) and legislation adopted under Article 16 of Directive 2000/60/EC of the European Parliament and of the Council

Accordingly, the relevant information does not have to be included in applications for authorizations (Article 59(6)).

The recital to *Article 57 – The Granting of Authorizations* (REACH, 37), states as follows:

> The Commission shall be responsible for the granting or refusing of authorisations. The authorisation application and decision shall not address risks to human health and/or the environment of emissions of the substance from an installation for which a permit was granted in accordance with the IPPC Directive (Directive 96/61/EC) or from a point source governed by requirement for prior regulation under the Water Framework Directive (Directive 2000/60/EC) or arising from the use in a medical device as these emissions are adequately controlled under other Community instruments which are applied by the Member States. Therefore, this is necessary not to interfere with such other competences and to avoid differences between the decisions taken under different regulatory regimes as well as the resources in examining an impact twice.

This stipulation can be regarded as a delineation of the administrative decision making responsibilities of, on one hand, the Commission in regard to authorizations, and on the other, the competent national authorities in regard to sectoral environmental regulations.

Thus, the effects of substances as determined by the competent authorities of the relevant Member States on the basis of the IPPC and Water Framework Directives are not

taken into consideration when authorizations decisions are made.

However, this stipulation is in direct conflict with the general risk management thrust of REACH, which is reiterated in the recital to Article 57 (REACH 37), which states as follows:

> "Authorisations shall be granted if the risk to human health and the environment posed by a use is adequately controlled."

It follows from this stipulation that immissions regulations will nonetheless be a factor in subsequent authorization reviews pursuant to the IPPC and Water Framework Directives, as Article 58 (4) and (5) stipulate:

> If an environmental quality standard referred to in Directive 96/61/EC is not met, the authorisations granted for the use of the substance concerned may be reviewed.
> If the environmental objectives as referred to in Article 4(1) of Directive 2000/60/EC are not met, the authorisations granted for the use of the substance concerned in the relevant river basin may be reviewed.

The recital to Article 58 states as follows in this regard (REACH, 37 f.):

> Authorisation decisions may need to be amended or withdrawn as a result of a review which can be done at any time when there is a change of circumstances. Such a change of circumstances can for example be changes in the scientific basis for an authorization decision or that environmental quality objectives as defined under the IPPC Directive or Water Framework Directive are not met because of diffuse emissions to water or the air. Emissions from point sources however are dealt with under those Directives.

In terms of the interface between plant-related and water legislation, REACH makes what can be regarded as an administrative distinction between the *immission*-related quality standards pursuant to other regulations[166] and the *emission*-related requirements to which point sources are subject. It is probable that in the interest of simplifying the initial registration process, the framers of Article 57

[166] However, it should be noted that the IPPC Directive does not yet contain a separate immissions-related quality standard, and instead refers to the quality standards of other regulations (see Articles 10 and 13 of the IPPC Directive, and section E1c), p. 63 herein). Thus, it is probable that these referenced quality standards are meant here as well.

apparently operated on the assumption that activities that fall within the purview of the IPPC Directive and Water Framework Directive entail no risk, an assumption that is not borne out by substance regulation efforts to date.

If it is determined that these issues pertaining to the control of Existing Substances will not be addressed under the REACH system, it will be necessary to establish regulatory interfaces that can be used to implement and execute any risk reduction measures within sectoral environmental regimes. REACH does not provide for such interfaces, however, i.e. ones that would allow substance related data to be routed to the relevant actors.

Thus, in contrast to the current system, under REACH it will be completely impossible to implement emissions reduction "recommendations" (which are in any case relatively non-binding) on the basis of sectoral regulations. Full responsibility for this regulatory realm would be shifted (albeit under the auspices of Community legislation) to the competent Member State authorities or operators concerned. Accordingly, there is no basis upon which to implement the requisite monitoring and information exchange mechanisms that would allow the progress of point source reductions to be tracked.

Concerning environmental quality objectives the crucial point remains unresolved (see section E1c) p. 63 and section E2, p. 65) in that immissions values for other sectoral regulations have not been defined for most of the Existing Substances that fall within the purview of REACH; nor is this situation likely to change substantially at any time in the near future. Moreover, normally the permission procedure governed by sectoral regulations does not take into account the effect based immission thresholds that are generated during the evaluation of Existing Substances. What appears to be the case instead is that under REACH, the competent authorities of the Member States will continue to base their actions on what is in the best interests of the pollution emitter.[167]

[167] See also the assessment of the German Advisory Council on the Environment (SRU) (Umweltgutachten 2004, No 1032), which states as follows: "Basing general exceptions on the provisions of the IPPC and Water Framework Directives is not an ideal solution since both regulations leave a great deal of leeway when it comes to ascertaining limit values. In our view, chemicals legislation should prioritize the

It is also unclear how information is to be obtained for use in authorization reviews that determine whether immissions quality standards are being maintained.

Hence there is a need for a reciprocal exchange of information. The data obtained for purposes of granting chemical authorizations should be made available to the competent authorities of the relevant Member States as stipulated by the IPPC and Water Framework Directive, while at the same time the Member States should make available their monitoring data for both immissions and point source emissions to the European Chemicals Agency. This should be realized (a) for all applications and production processes for which a specific risk or need for action is identified and (b) for both authorization reviews and the implementation of sectoral regulations.

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enablement of general decisions regarding usage, prohibitions and restrictions while still taking into account the hierarchy of the various legal instruments. Such restrictions and prohibitions should be implemented both upstream and downstream of emissions monitoring mechanisms.”

c)
Registration evaluation

Article 18 of REACH stipulates that the European Chemicals Agency must evaluate each registration that is submitted. Depending on the substance volume involved, Articles 9(a) and 9(b) require, respectively, a technical dossier and a chemical safety report, pursuant to Article 13.[168]

Both the technical dossier and chemical safety report must disclose all chemical risk irrespective of which sectoral regulations the substance is subject to. Accordingly, the scope of the Agency's evaluation is extensive as well. In the first stage, the technical dossier is checked for completeness only, while in the second stage the chemical safety report stipulated by Article 13 of REACH is reviewed in detail.

Substance stewards' documentation obligations and the attendant evaluation by the Agency are less extensive at this stage, but for this reason are more comprehensive than for an authorization.

d)
Conclusions

Under the REACH system, the responsibility for risk assessment and management falls squarely on the shoulders of substance stewards, with the competent authorities playing only a "supporting" role in this regard. In this scheme of things, depending on the substance volume involved, substance stewards are obligated to disclose and document all possible substance-induced risk during the registration process.

Inasmuch as the authorization requirement for a substance of "particular concern" under REACH will presumably not limit substance stewards' basic REACH-related obligations," a yawning gap between these obligations and the consequent documentation emerges in that retention of the basic obligation to manage substance risk comprehensively narrows the scope of (a) the risks that *actually have to be disclosed* and (b) the risk reduction measures that have to be *undertaken* when an authorization threshold is reached. This is due to the fact that in this scenario the emissions-

[168] Article 9(b); see also section F1a) p. 77 herein.

related risk reduction measures that fall within the purview of the IPPC and Water Framework Directives are not taken into consideration. REACH does not define an interface between itself and these regulations in regard to (a) the question as to whether the point source emissions limits for a specific substance are lower than its predicted no effect concentration (PNEC) and (b) the issue of coordinated monitoring of emissions and immissions and the consequent exchange of information between the European Chemicals Agency and the competent authorities of the relevant Member States.

It would be possible to implement other regulations at the third level of EU or Member state intervention (i.e. general restrictions) that would apply to the application domains of the aforementioned sectoral directives. However, in view of the elevated political and administrative transaction costs associated with substantive measures in this realm, and the fact that such measures have thus far been most notable for their absence, they are unlikely to be instituted to any great extent in the near future either.

3

Evaluation

One clear fact emerges from the investigation of the current situation: the regulatory interface problem has been identified under REACH, but a solution has yet to be found.

Still unclear is exactly how risk assessment data (extensive amounts of which are to be gathered by the manufacturers but are then evaluated to a limited extent only by the competent authorities) is to be applied to risk reduction measures:

- In terms of the risk management that will have to be ensured by the substance stewards it is unsettled, how the risk management strategies that have been identified shall provide an incentive for downstream actors to put them into practice. There is a risk here of a third-order implementation deficit.
- The following observations have a crucial bearing on the intervention options available to government authorities:
  - The scope of general restrictions on manufacturing conditions could be expanded relative to the restrictions that are currently in force. This mechanism could be applied to the management of point source emissions only if this problem exists in a significant number of Member States, because otherwise there would not be sufficient need for Community-wide instruments.

- Point source emissions will not be a criterion for substance authorization decisions since it is apparently assumed that these emissions will be adequately controlled by implementing the Member State rules that would come into force under the IPPC and Water Framework Directives. However, the REACH regulation lacks the procedural and informational mechanisms that would be needed in order to achieve this goal.
- Immissions regulations pursuant to the IPPC and Water Framework Directives will play a role in the authorization review process. The European Chemicals Agency is entitled to review authorizations in the event the relevant immissions limits are exceeded. REACH lacks a system that would ensure that the competent Member State authorities submit the required information to the Agency.
- The Agency has relatively little influence on the registration procedure since its main role is to check the completeness of the documentation submitted. It remains unclear whether the more extensive documentation required by Article 13 of REACH would translate into more extensive evaluation by the competent authorities

Hence, administrative mechanisms under REACH for risk monitoring and assessment, as well as risk reduction, and the regulatory interface between these mechanisms and substance stewards' basic obligations, appear to be poorly conceived.

REACH also suffers from an "instrument gap" that is attributable to the fact that the interface problem has not been remedied at the legislative level. Moreover, there are also interface problems in regard to sectoral instruments at the legislative and administrative levels. Hence, primarily first- and second-order implementation deficits are involved here.

REACH and the consequent shifting of responsibility for chemical risk management to the substance stewards will give rise to third-level regulatory interface problems. The extent to which these problems can be managed successfully will be determined by the nature of the institutional scenarios that evolve at the legislative and administrative levels. The question also arises as to which inducements (preferably ones that entail minimal expenditures) will prompt new stakeholder groups to reduce risk effectively.

Recommendations aimed at remedying the regulatory interface problem should be based on the incentive situations that are likely to evolve for those substance stewards most directly involved in risk reduction and the options available to them

for the implementation of such reductions for downstream applications. It is certain that the regulatory interfaces that have been identified between Existing Substances on one hand, and point source-related legislation and the consequent monitoring mechanisms on the other, will play a major role in this regard. The conclusions in section E (p. 56 ff.) and recommendations in section H2 (p. 100 ff.) could come into play here because the interface problem in regard to current sectoral environmental law will remain unchanged. The viability of the consequent modalities for government intervention under REACH will only be ascertainable after the effectiveness of the new self-regulation regime has been measured.[169]

As for the interfaces with other sectoral regulations, it should be borne in mind that under REACH, risk reduction strategies will no longer lie within the purview of the competent authorities. Before PNEC values determined by the substance stewards are integrated into the administrative implementation procedures for other sectoral regulations, it would be advisable to validate these parameters for more than just mere plausibility, particularly in view of the fact that government authorities are ultimately responsible for protecting the legal interests of all actors and resources concerned. In view of the interdependency of the factors involved and the need for uniform legal instruments, the aforementioned validation should be realized by the Community institutions under whose purview substance legislation falls.

[169] This issue, which lies outside the scope of the present report, is (as mentioned previously) the subject of a separate invitation to tender from the Federal Environmental Agency (Umweltbundesamt) (FKZ 204 67 462/04).

G

Transition from the Existing Substances Regulation to REACH

Another regulatory interface problem arises in connection with the transition from the Existing Substances Regulation to REACH in that the lessons that have been learned to date should be applied to the new regulation and should not go to waste. In the following, we will first describe the interim strategies defined by REACH for this transition (subsection 1) and then discuss how the groundwork could be laid for the transition under the Existing Substances Regulation (subsection 2).

1

Interim strategy under REACH

Three main questions arise in connection with an interim strategy under REACH: (1) After the REACH regulation goes into effect, will current competences form an adequate basis for implementation of the lessons learned from the Existing Substances regime (section a, below)? (2) How will the administrative mechanisms that were established under the Existing Substances Regulation be carried over into the new administrative context (section b, below)? (3) Although under REACH the substance stewards will be undertaking most risk reduction measures on their own, these measures are still subject to evaluation and authorization by the competent authorities. How can the risk reduction expertise that has been acquired through administrative collaboration be applied productively to these processes under REACH (section c, below)?

a) Carrying over competences to REACH

Under the Existing Substances Regulation, the process of elaborating risk reduction strategies culminated in Commission recommendations whose purpose could be either to elaborate general restrictions or to recommend that additional activities be undertaken.

aa)
Legal basis for restrictions

Article 132 of REACH defines the following interim procedure for the elaboration of restrictions under the current Existing Substances Regulation:

> Within 18 months of the entry into force of this Regulation, the Commission shall, if necessary, prepare a draft amendment to Annex XVI in accordance with either of the following:
> a) any risk evaluation and recommended strategy for limiting risks that has been adopted at Community level in accordance with Article 11 of Regulation (EEC) No 793/93 but for which Community measures to limit those risks have not yet been taken;
> b) any proposal, which has been submitted to the relevant institutions but has not yet been adopted, concerning the introduction of restrictions under Directive 76/769/EEC.

REACH justifies this on the following grounds (REACH, Article 50):

> Extensive work has been performed under Directive 76/769/EEC and Regulation (EEC) No 793/93. It is likely that some of the restrictions identified in these pieces of legislation will not have been taken all the way through to a Commission decision before this Regulation comes into force, including repealing Directive 76/769/EEC and Regulation (EEC) No 793/93. This enables such restrictions to still be brought forward and implemented without having to go through all the new procedures set out in this Regulation.

This provision ensures that restrictions that were in process but had not yet been adopted under the Existing Substances Regulation can still be enacted.

bb)
Recommendations pertaining to point source emissions

The REACH regulation does specify what should be done with point source measures that proved necessary under the Existing Substances Regulation.

In ascertaining how this loophole can be closed, it should be borne in mind that the measures concerned are published solely as recommendations that advise, but do not require, those concerned to follow a certain course of action.[170]

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[170] See EuGH, Rs. 322/88 – Grimaldi – Slg. 1989, 4416.

Article 211 indent 2 EC sheds some light on the legal basis for such recommendations and the procedure that is to be followed in their regard:

> In order to ensure the proper functioning and development of the common market, the Commission shall:
>
> - ensure that the provisions of this Treaty and the measures taken by the institutions pursuant thereto are applied;
>
> - formulate recommendations or deliver opinions on matters dealt with in this Treaty, if it expressly so provides or if the Commission considers it necessary;
>
> - (…)

Thus, the Commission can formulate recommendations pursuant to the treaty and secondary legal instances, as well as when the Commission "considers it necessary" to do so. This means that during the transitional phase and for such legal instances, the Commission is also free to formulate Existing Substances-related recommendations that do not constitute a "restriction" pursuant to Article 132 of REACH.

Consultation of other EC institutions is not required. However, since this involves the results of Existing Substances assessments that were realized under Directive 793/93, the Commission can also bring to bear the committee consultations referred to in the Directive.

cc)
Conclusions

No instrument gap in regard to competences is foreseen during the transitional phase, which means that the Commission is free to take regulatory action during this period. Whether it will avail itself of this opportunity is presently unclear.

b)
Administrative transition

A clear determination should be made as to how long the Existing Substances committees will continue their work under REACH.

The draft regulation pursuant to Article 132 of REACH can be submitted within 18 months of the entry into force of the REACH regulation. This circumstance alone is reason enough

to refrain from terminating committee work on Existing Substances immediately after REACH comes into force.

However, Article 134 of the current draft of REACH repeals the directives that form the legal basis for the regulation of Existing Substances. This means that 20 days after REACH is published in the Official Journal, the legal basis for the committees' work would be abolished.

However, it should be borne in mind that it will take time for the Agency to get up to speed from an administrative standpoint. Article 131 stipulates that the Commission is to fulfill the functions of the Agency; the Commission arranges the establishment of the Agency. Within 18 months, the Agency is to "notify the Commission that the Agency is ready to assume its functions" under the REACH regulation.

In order to avoid an administrative vacuum and ensure a smooth transition from the current Existing Substances system to REACH, the Existing Substances directives can be repealed after the new administrative structures are in place.

The legal basis for this might be that one of the REACH provisions pertaining to the transitional period stipulates that the Existing Substances directives will apply for 18 months after REACH comes into force.

c)
Carrying over risk reduction expertise to the REACH regime

REACH will shift responsibility for the management of chemical risk to the substance stewards, while government's role will consist of evaluating registration documents, determining priorities and issuing authorizations for Existing Substances, and promulgating general substance restrictions.

This new arrangement raises the question as to how the expertise that has been acquired in regard to risk assessment and evaluation can be transferred to the new stakeholders.

The committee referred to in Article 130 of REACH (as well as any subcommittees and working groups that are needed) will provide a certain measure of continuity for cooperation between the Commission and Member States, and this in turn will promote a smooth information transfer process.

As for cooperation between the Agency and experts from the Member States, Article 72 of REACH stipulates that the committees and Forum should determine the extent to which experience can be transferred.

However, the arrangement concerning substance stewards – who will be the most important actor under REACH – is far from optimal in that they will be elaborating risk assessments and the "applications" of risk reduction measures, although this was realized by government agencies up till now. Thus REACH assigns tasks to a somewhat heterogeneous group of stakeholders that has never before carried out such tasks in this setting and for this purpose.

This shifting of responsibility also relocates into the realm of private-sector environmental management the lion's share of a series of problems that were heretofore the province of government, including information gathering and evaluation, communication with other actors, and building cooperative relationships.

Although it can be justifiably argued that the REACH system is merely elaborating legal and procedural requirements for a sphere of responsibility that manufacturers and importers have always assumed anyway, undertaking these responsibilities will entail considerable transaction costs that can probably be reduced if expertise can be successfully transferred from the actors in the current Existing Substances process to the new actors under REACH.[171]

2

Termination of Existing Substances work

The Commission has elaborated a procedure for dealing with the results of work that was carried out under the Existing Substances Regulation. [172]

The Commission's proposal came to the following conclusion in regard to legislative measures:

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[171] This was probably the underlying intention of the Guidance Document, which provides substance stewards with standards and other support that go beyond those available in the REACH Annexes (see Guidance Document 204 67 462/04).

[172] See also: Commission's Proposal for rapid agreement of 'Commission recommendations' for Regulation (EEC) 793/93.

Commission recommendations in the future should be mainly focussed on legislative measures at the Community level to be taken under existing law.

The following examples of possible measures are provided:

- development of a Community Occupational Exposure limit;
- a marketing and use restriction under Directive 76/769/EEC;
- inclusion of the substance in the ongoing work to develop guidance on Best Available Technologies (BAT) under Directive 96/61/EC (Integrated Pollution Prevention and Control); or
- consideration if the substance should be included in the priority list of Directive 2000/60/EC (Water Framework Directive).

Although this is not an exhaustive list, it is noteworthy that the document primarily addresses the Commission's existing spheres of responsibility, including legislative measures at the Community level, as well as continued work on the list of priority substances pursuant to the Water Framework Directive, and work on BREFs by the European IPPC Bureau in Seville within the framework of the IPPC Directive.

On the other hand, under the Existing Substances Regulation, the rapporteurs' risk evaluations and risk reduction strategies had to include point-source reduction measures that pertained to only a limited number of sources and thus did not reach the threshold that would constitute a Community-wide procedure. If the Commission adopts the aforementioned proposal (which they of course can if they wish to), specific emissions reduction measures for problematic point sources will be off limits, despite the fact that according to the risk reduction criteria for Existing Substances, these measures have proven to be highly effective, practicable and readily amenable to monitoring.

This would mean that a highly useful risk reduction tool would be excluded from consultations. Although it is argued in some quarters that this change is justified by the fact that spheres of responsibility have been reconfigured, it is nonetheless the case that under REACH, local authorities will still be responsible for monitoring and controlling point source emissions and the consequent immission scenarios, although operators are required to (a) meet basic obligations in regard to water and installations and (b)

carry out the consequent risk reduction measures in their own responsibility.

Any risk reduction measures that have been or are elaborated for Existing Substances should be carried over to new risk reduction strategies, irrespective of whether such measures were introduced by industry actors or were prompted by government interventions for purposes of inducing compliance.

Thus, it would be advisable to incorporate into the procedure for the assessment of possible risk reduction measures (a) the Community-wide coordination measures from Annex X of the Water Framework Directive (which have proven effective in the medium term); (b) the BREFs pursuant to Article 16 of the IPPC Directive; (c) the other point source reduction measures that are based on the instruments in the latter Directives (e.g. as per Article 13 of the IPPC Directive[173]).

[173] See section H2b), p. 99.

H

Ways to eliminate the “instrument gap”

This section recapitulates the findings of the report as a whole. After presenting a general overview of the issues involved (subsection 1), we describe remedies for the regulatory interface deficit in Community substance legislation (subsection 2). This is followed by recommendations for further action (subsection 3).

1

General overview of the problem

Within the Existing Substance Regulation risk information is generated with high expenditure regarding chemical substances that are currently in use (Existing Substances). This knowledge has traditionally formed the basis for the elaboration and evaluation of various risk reduction strategies. The current Existing Substances Regulation (Directive 793/93/EC) has established a coordinated Community-wide process whereby one Member State takes on the role of a rapporteur for a particular Existing Substance, for which the Member State then evaluates risk and elaborates (if necessary) risk reduction strategies on the basis of industry and supplier data, scientific data, and data from the competent government authorities.

Risk for man and the environment can occur within the framework of manufacturing, processing, commercial use, consumer use or disposal. Where Community-wide control of chemical substances is needed, restrictions on use and/or marketing can be imposed.[174] The same holds true when emissions to air or water reach a level that appears to indicate that mandatory Community regulations are warranted. Such legislation can be enacted as quality objectives, quality standards or emission standards within the framework of air quality Directives or Water Framework Directive, or in an instrument pertaining to a specific installation (e.g. in a Directive that targets a group of substances such as

[174] REACH also allows for the enactment of regulations regarding manufacturing conditions (see section F2a), p. 81).

the VOC Directive).[175] The elaboration and enactment of such legislation requires strong administrative and political effort. However, in the interest of achieving a high level of Community-wide protection (see section B1, p. 3) and creating a level economic playing field within the Community, authority to enact such environmental legislation should be used without stint whenever necessary. This holds true as well for restrictions on chemicals and product regulations, since such measures provide optimal opportunities to reduce pollution efficaciously.[176]

Nevertheless, in certain cases there are justifiable reasons for neither resorting to the instruments of chemicals regulations nor enacting mandatory Community-wide legislation. But at levels below harmonized Community standards, there are cases of substance-related risk that necessitate extensive action. This can occur, for example, when point sources release emissions that appear to be a cause of serious concern for the environment and human beings. The decisive threshold within the Existing Substance risk characterization is the predicted no effect concentration (PNEC), which is defined on the basis of a detailed test protocol. Under the Existing Substances Regulation, at the Community level the attendant evaluation process brings into play the competent authorities at the Technical meetings as well as a toxicological quality control process in the form of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE).[177]

It would make sense from a practical standpoint to apply the **immissions assessment standards** elaborated using such peer review mechanisms to the implementation of policies in other environmental sectors in the Community as well. However, no legislative or administrative remedies have been devised for this interface deficit.

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[175] On the issues surrounding the definition and implementation of environmental quality objectives, see Rehbinder 1997 and Barth/Köck 1997.

[176] On various ways to manage substances via product regulations, see Führ 2000.

[177] The Committee’s role in the risk evaluation process is codified in Directive 1488/94. The Committee was recently renamed the Scientific Committee on Health and Environmental Risks (SCHER) (European Directive of 15 June 2004).

Necessary and reasonable **point source emissions reduction measures** that were developed in the risk reduction strategies should be adopted more productively in the implementation of national provisions that execute Community legislation. Eschewing Community-wide chemicals regulations is only appropriate if it promotes the development of alternative point source reduction strategies. The rapporteurs assumed that the competent Member State authorities can manage specific instances of chemical risk competently and effectively using existing instruments from the IPPC and Water Framework Directives. This would be in keeping with the Community principles of subsidiarity and necessity (Article 5(2) and 3 EC), the latter of which states that where two comparable and suitable measures are available for achieving a specific goal, the solution selected should be that which impinges least on the legal rights of substance manufacturers and users, as well as other stakeholders.[178]

However, if these comparative moderate means should prove to be unfeasible for one reason or another, the question arises again as to what action should be taken on the basis of chemicals regulations at the Community level. In other words, can Community legislators safely assume that chemical risks will be eliminated by some other means and thus avoid imposing drastic general restrictions (see the Navy Blue case history, p. 42 ff.)? On the other hand, in the absence of point source regulations that provide the desired results, specific substance regulations must be imposed, although this can also impose a greater burden on the business segment concerned.

The “instrument gap” hypothesis has turned out to be a real phenomenon, albeit in a somewhat modified form. Although Community industrial installation and water legislation allow for measures that can help reduce substance risk, there are no mechanisms that would allow for coordination of the nexus between Existing Substances rules and sectoral environmental legislation. Thus, a “first order” implementation deficit can be said to exist (see section B2,

[178] The principle of necessity is also the most important criterion for the determination of “proportionality.” On this (and interconnections with the “economic principle”) see Führ 2003, 357 et seq.

p. 5) that is attributable to shortcomings in the interfaces between the various sectoral regulations.

2

Overview of possible solutions

Against this backdrop, the question arises as to where and by what means institutional conditions are amenable to change. What is needed are effective links between the chemicals regulations and other environmental legislation. This applies to the coordination of Community-level interfaces with other sectoral regulations as well as to the integration of such links with measures realized by Member State authorities. Such efforts would also necessitate the elimination of “second order” interface deficits.

There are three possible approaches to eliminating the regulatory interface problem:

- Chemicals regulations could be given a dominant role relative to other legislation.[179] Although this would allow for the enforcement of chemical risk reduction need, it would subject these measures to a considerable governance burden.
- At the other end of the scale is the current solution whereby chemicals regulations and other environmental legislation scarcely interface at all, thus provoking the implementation problems described in this report.
- Another integrating solution would be to leave the various types of legislation intact and define interfaces that would allow for inter-regulatory “interchange.”

In view of the unlikelihood that chemicals regulations will be prioritized in Community environmental legislation at any time in the foreseeable future,[180] the discussion that follows focuses on the latter interface-oriented solution.

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[179] See for example the proposals advanced by Gebers/Führ/Wollny 1993 (Ökologische Stoffwirtschaft - Grundanforderungen an eine Stoffflußregulierung) and Rehbinder 1995 (Konzeption eines in sich geschlossenen Stoffrechts); see also Führ 1997.

[180] The other criticisms that have been leveled at this solution are only touched upon in the current report. The main criticism, apart from the aforementioned administrative “overburdening” of chemicals laws, is that current sectoral regulations have dedicated purposes for good reasons and have developed specific implementation structures and cultures that serve these purposes.

This discussion addresses the following questions (among others):

- At which point in the execution of sectoral regulations should the results of the evaluations of Existing Substances be “integrated”?
- To what extent should these results be legally binding and how much leeway should authorities be given in terms of implementing such measures?
- Which monitoring mechanisms could successfully track the effectiveness of this type of implementation?

The regulatory interface problem cannot be resolved unless suitable nexuses are created in chemicals regulations, as well as in installation legislation and environmental media law (see overview on p. 103. Monitoring and disclosure mechanisms are also needed.

A determination should also be made as to how such nexuses would be structured under REACH and how the regulatory transfer from the Existing Substances Regulation to REACH will be accomplished (interim strategy).

a)
Interfaces with current chemicals regulations

The following interfaces could help to eliminate the current lack of interfaces with the Existing Substances Regulation:

- Effect based thresholds (PNECs) for immissions:
  Definition of the relevance of these thresholds for other regulations and implementation of these thresholds in the Member States
- Emissions reduction measures that are deemed effective, necessary and reasonable in the risk reduction strategies:
  Definition of the relevance of these measures for the elaboration and implementation of point source legislation in the Member States

The elaboration of regulatory interfaces entails an essentially unresolvable dilemma, which is as follows: The more closely interrelated the results of the substance evaluation with the need of action, the greater the resulting administrative burden on the Existing Substances procedure, since a balancing of interests must be incorporated into the procedure. Conversely, a loose interconnection (as in the current system) leads to far-reaching implementation shortcomings. Thus, proposed solutions to the interface problem should strike a balance between these two extremes in such a way as to promote effective risk reduction.

b)
Interfaces in industrial installation regulations

Nexuses could be established between current immissions and emissions Directives as already implemented in industrial installations regulations.

The following approaches – with stepwise declining binding force – could be applied to *immissions* thresholds:

- Insofar as Community-wide controls are needed, these thresholds could be incorporated into air quality Directives and the list of priority substances in Annex X of the Water Framework Directive.
- A weaker regulatory interconnection could be realized by implementing the following two interfaces (in the guise of a statement to the effect that exceeding the threshold limits defined in the risk assessment would automatically lead to the assumption that industrial installation thresholds were also being exceeded):
  - Exceeding the PNEC limits would automatically indicate the presence of "significant" pollution in accordance with IPPC Directive (Article 13(2) second indent).
    An incremental scale for the extent of exceedance would also have to be developed to phase in government measures.
  - Exceeding PNEC limit values would indicate that point source pollution reduction measures are to be realized pursuant to Article 10(3) of the Water Framework Directive.
    An incremental scale for the extent of exceedance would also have to be developed to phase in government measures.
  - In order for these measures to be realized, PNEC threshold values would have to be documented using a "paralegal" mechanism (i.e. on the web site of the future European Chemicals Agency) so that the relevant information would be readily accessible to operators, local authorities and government agencies.

In regard to the *emissions* reduction measures – which have been exhaustively reviewed and found to be adequate – a regulation could be elaborated requiring that all risk reduction strategies be consistent with the principle of proportionality (presumption of conformity). This would in turn induce a BREF "spinoff" effect that would remain in force until the subsequent BREF revision.[181] This would of course mean that risk reduction strategies at the Community

[181] For this solution as well, an appropriate documentation system might also be needed, particularly in order to establish the requisite interface between Community and Member State versions of BREFs.

level would have to be elaborated on the basis of a dedicated procedure, although from the legal standpoint of the current Existing Substances Regulation, this would only represent a minute step forward for the already relatively mature committee procedure (and would require the participation of the scientific committee).[182] Under REACH, such measures would have to be elaborated by the Agency on the basis of risk management strategies developed by substance stewards.

All such interfaces with industrial installation instruments would be elaborated on the assumption that the competent authorities would evaluate immissions levels, the technical particulars of specific installations, and any new information acquired at their own discretion and pace. In the interest of treating all pollution emitters equally, the risk reduction implementation system should be phased in incrementally (on the model of the retrofitting existing installations program as per part 6 of the "Technical Instructions on Air Quality Control"[183]) that would be consistent with the principle of proportionality and would codify execution by public authorities. Monitoring mechanisms would also be needed for this approach (see section H2d) p. 109).

All of these proposals are based on the assumption that the point sources concerned would fall within the purview of a Community industrial installation regulation, i.e. in most cases the IPPC Directive. In the case of SMEs or other installations that either use or process chemicals[184] and are

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[182] Another question that arises in this regard is whether Commission committees would be able to agree on the particulars of risk reduction strategies.

[183] Technische Anleitung zur Reinhaltung der Luft – TA Luft. The Technical Instructions on Air Quality Control provide authorities with a modern instrument for controlling air pollution that creates greater legal and planning certainty. The immissions section (immission means the impact of pollutants on plants, animals and man) of these instructions contains provisions on protecting the public from unacceptably high pollution levels from industrial plants. The emissions section (emission means any discharge of substances, energy or radiation into the environment) contains limit values for precautionary action against harmful environmental impacts and specifies corresponding emissions values for all relevant air pollutants. Both new and existing industrial plants are taken into consideration. Existing plants must also be upgraded to the best-available technology following appropriate transition periods.

[184] See section E1a) p. 57

not subject to the provisions of the IPPC Directive, it might be advisable (on the model of Article 22 ff. of the German Immission Control Act (BImSchG)) to elaborate basic obligations and to require the Member States to enforce quality standards following the Existing Substanc evaluation for these installations. This provision already exists in water legislation but does not apply to other emissions.

c)
Interfaces in environmental media legislation

In terms of environmental media regulations, interfaces are mainly needed for quality standards. To some extent these overlap with regulations governing industrial installations. But when it comes to diffuse emissions that do not fall within the purview of a specific industrial legislation and are not subject to Community-wide chemical restrictions either, further call for action is given which, for the aquatic sector (the main sector concerned in the case study substances), would have to be implemented via the Water Framework Directive. Interfaces should be identified in soil protection or waste legislation for waste water processing residues, which have also proved problematic for the case study substances.[185]

The following interfaces could be elaborated for water legislation:

- If Community-wide action is required:
  Inclusion in the list of priority substances pursuant to Annex X using the Existing Substances procedure as a basis
- Adding the substance in question to List II of Directive 76/464/EEC (Dangerous Substances Directive)
- Classification as a substance under Annex VIII of the Water Framework Directive, which would entail an evaluation and measures in accordance with Articles 5, 10 and 11 of the Water Framework Directive.
- Inclusion in local monitoring systems of dangerous substances that are discharged in significant quantities (Annex V No 1.3.2 of the Water Framework Directive)

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[185] See for example (in regard to the criteria defined in EC Directive 91/689/EC): Landesanstalt für Umweltschutz Baden-Württemberg (Ed.), Ecotoxicological characterization of waste – Method development for determining the “ecotoxicological (H14)” risk criterion, Karlsruhe 2004.

Specific interfaces would also have to be defined between the aforementioned instruments and substance assessment results. An indexing mechanism should be incorporated into water legislation (similar to the mechanism defined for installation regulations) that promotes compliance with PNEC thresholds as a minimium standard. A procedure should be elaborated for the transfer of pollution scenario expertise acquired under the Existing Substances regime to the local authorities. Lastly, a Community procedure should be elaborated for coordination of the Annex VIII substance classifications.

Conversely, an information interchange system should be established between water and chemical authorities so that the latter can monitor the progress of risk reduction and risk management measures under REACH.

Overview of the interfaces between substance, environmental media and industrial installation legislation

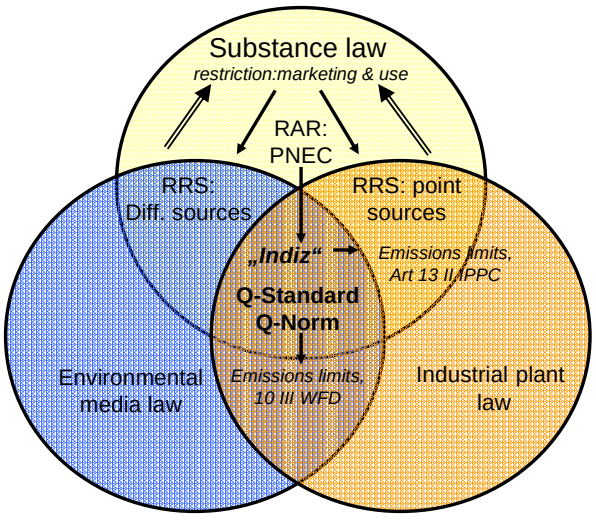

Figure 7: Overview of interfaces

d)
Transparency rules for monitoring and information exchange

Finally it would make sense to strengthen monitoring instruments with a view to keeping all those involved in reducing chemical risk[186] updated. Trans-regulatory monitoring mechanisms should be elaborated regarding the success (vis-à-vis environmental quality standards) of risk reduction strategy implementation.

Regarding emissions reduction measures aimed at IPPC Directive installations an interface could be implemented at the Community-level emissions registers (EPER and PRTR) that are currently being established. Such measures should allow for the monitoring of individual point sources.

The legal basis of EPER would have to be modified in such a way that Existing Substances which pose a risk from the chemicals regulations standpoint would be included in a "simplified" priority substance list procedure, with the result that emissions of these substances would have to be reported. This would in turn increase the dynamics of reporting data that industry is required to submit.

It may also be worthwhile to establish internal company reporting obligations. If interfaces with the emissions registers are established, suitable internal company measures will have to be taken as well. Experience with this type of reporting obligation has shown that merely gathering data for external reports on an ongoing basis has an impact on company processes. Establishment of a dedicated substance flow management system for each installation operator (along the lines of Article 16 ff. of the German Dangerous Substance Directive) might also be worth considering. This would operationalize operators' basic obligations pursuant to Article 3(a) of the IPPC Directive and would promote a cross-media and integrated approach to deployment of the best available techniques for the design and operation of industrial installations. A substance flow management system of this type could also form the basis for an interface to

[186] This includes all Community and Member State authorities that implement Existing Substances procedures pursuant to 793/93/EEC, as well as the relevant substance stewards (manufacturers and importers). The latter will be more actively involved in such implementation under REACH than is the case under the present system.

substance stewards' risk reduction obligations pursuant to Articles 13 and 34 of REACH.

e)
The situation under REACH

The question as to how emissions reduction is to be reliably achieved for point sources will still have to be addressed after REACH comes into effect. The interface problem has been recognized for the small minority of substance authorizations, but as for the majority of chemicals, remains unsolved (see section F3 p. 90).

Proposed solutions to the interface problem at the administrative and legislative levels can be found in previous sections of the present report. However, it should be noted that under REACH, risk reduction strategies will be elaborated by the substance stewards rather than government authorities. Thus, before PNEC values are applied to the administrative implementation of other sectoral regulations, it must be determined to what extent scientific validation of the threshold is necessary.

In view of the input to which substance stewards will be subject under REACH, the question arises as to how they will be able to influence the way other stakeholders in the chemical supply chain deal with the substances they use or process. Inasmuch as this involves a scenario whose structure differs entirely from that discussed in the present report, it will not be considered further.

f)
Interim strategy

Enactment of the REACH regulation will give rise to a de facto interface between REACH and former legislation. Under this new regulatory regime, the issue of competences will have to be resolved, which will entail determining the legal basis for the implementation of risk reduction measures that have been elaborated under current chemicals regulations. The other issue that must be resolved if the new Regulation is to be effective is how the risk reduction strategy expertise that has been acquired by the competent authorities can be leveraged productively within the new legal framework. In other words, mechanisms should be devised that ensure administrative continuity.

Article 132 of REACH opens up the possibility of enacting general restrictions pertaining to the implementation of risk reduction strategies that were developed prior to the enactment of REACH. However, the REACH provisions governing the transitional period do not allow for the realization of point source measures. Nonetheless, pursuant to Article 211 EC, the Commission is still authorized to issue point source related recommendations, even after repeal of the Existing Substances Regulation. In this sense, the enactment of REACH will not resolve the interface problem that hampers practical realization of point source reduction measures. Thus, the proposed solutions to the interface problems that were formulated above also pertain to the transitional phase of REACH.

The REACH risk reduction instruments will not become effective immediately after the Regulation comes into force. Pursuant to the REACH provisions governing the transitional period, this will hold true even if the problems engendered by the transition are resolved from the standpoint of both substance stewards and the new administrative apparatus that will be instituted under the Regulation.

REACH provides for an 18-month transitional period for purposes of constituting the Agency’s organizational structure and enacting restrictions pursuant to Article 132. In view of these circumstances, it would be advisable to allow an 18 month period so that (a) ongoing work on the priority list substances can be terminated and (b) the committees pursuant to the Existing Substances Regulation can continue their work. The legal basis for this might be a REACH provision (added as paragraph 2 in e.g. Art. 132) pertaining to the transitional period that stipulates that the Existing Substances regulations would apply for 18 months after REACH comes into force.

3

Recommendations pertaining to future phases of the REACH process

The previous section contains a series of proposals that could help to reduce chemical risk more effectively. In the following, certain aspects of the coming phases of the REACH process are discussed. Consideration is also given as to how the approaches suggested above can be used to reduce the scope of the regulatory interface problem in the REACH consultation process (section b).

a)
Prioritization of potential solutions

In order to elaborate a viable strategy for the regulatory interface problem, it will be necessary to decide which of the approaches described above should be applied.

It would be best for the rapporteurs (who in any case have no desire to anticipate the policymaking process) if regulatory nexuses engendered the least possible amount of friction between the various implementation traditions. In light of the dilemma alluded to above (see section H2a p. 104), it seems likely to provide the immissions-related[187] threshold PNEC a presumptive status rather than impose narrowly defined obligations for the administrative implementation of other sectoral legislation. This information instrument should be combined with the aforementioned disclosure and reporting obligations, as follows:

- The assumption that exceeding PNEC immissions limits constitutes an instance of environmental pollution should be codified. At the same time, it should be made clear that the observance of PNEC threshold values does not exempt the producer or importer from compliance with emissions regulations. An implementation management system should be devised that sets transitional time limits whose length is determined by the volume of emissions that exceeds PNEC limits.
- Point source emissions reduction measures that are in line with the TGD criteria for risk reduction strategies elaborated under the Existing Substances Regulation[188] should be considered as proportional and reasonable according to plant-related legislation as well, including the actions required thereunder. This will give local authorities more leeway to modify point source emission rules via permit conditions and make allowances for special cases and circumstances.

In addition, the competent authorities should be obligated to report the emissions reduction measures they have

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[187] It could not be determined within the scope of this report whether risk assessment under REACH will continue to develop emissions-related data. However, in terms of the REACH interim strategy, clarification is needed as to how emissions-related information from the current Existing Substances Regulation can be applied to the implementation of sectoral regulations.

[188] The criteria are as follows: effectiveness, practicality, economic impact, monitorability (see section E1b)cc), p. 62)

arranged for. Some reporting obligations are already codified in Member State industrial installation and water legislation, but these obligations encompass only a small number of all dangerous substances and are insufficient to document the success of chemical risk reduction measures and to monitor the progress of risk management within the framework of chemicals legislation. Thus a pragmatic approach should be devised that leverage the monitoring mechanisms and reporting obligations of sectoral environmental legislation. It would also be advisable to simplify the review procedure for substances in the EPER and PRTR registers taking into account new risk information due to the REACH process. This would allow for standardized Community-wide documentation of substance transfers pertaining to industrial installations.

The Commission's proposed[189] Directive pertaining to a Community-wide register of pollutant emissions should also be seen against this backdrop. Article 8 of this Directive also provides for the following new procedure in regard to the release of pollutants from diffuse sources:

> Article 8
>
> Releases from Diffuse Sources
>
> 1. The Commission shall establish the time frame, the format and particulars needed for the collection and transmission of information existing in the Member States on releases from diffuse sources in accordance with the procedure referred to in Article19(2).
>
> 2. The information referred to in paragraph 1 shall be organised such as to allow users to search and identify releases of pollutants from diffuse sources according to an adequate spatial desaggregation and shall include information on the type of methodology used to derive the information.
>
> 3. Where the Commission determines that no data on the releases from diffuse sources exists, it shall take measures to initiate reporting on releases of relevant pollutants from one or more diffuse sources in accordance with its priorities.

[189] COM(2004) 634 final.

This mixed regulatory approach depends to some extent on administrative self-responsibility[190] but gives authorities the option to apply immission-related risk information to substantiate stricter emission control technologies. The disclosure and reporting obligations of this instrument are additional incentives for authorities to take action and enable other stakeholders such as the European Chemicals Agency and members of the general public to obtain information regarding the success of risk reduction measures.

The conditions for proposed solutions to the regulatory interface problem should be defined at the legislative level as this will be an incentive for authorities to "implement" (Article 6 EC) point source reduction measures. Efforts to resolve the "instrument gap" and "first order" implementation deficit problem will also enhance the effectiveness of administrative processes, while the new conditions will greatly help to reduce second and third order implementation deficits.

b)
A proposed amendment of the REACH regulation

The changes in REACH proposed above could be implemented by simply adding, at an appropriate location i.e. Title XIV,[191] an "Article 131a" that would stipulate the following:[192]

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[190] This approach has been applied for many years in both the public and private sectors and is codified in law (see Führ 2003, 104 et seq. and 129 et seq.)

[191] The new provision could be added to Title XIV ("Transitional and Final Provisions") because this section of the law deals with the integration of REACH with existing sectoral standards.

[192] This solution would be preferable to an amendment in the Annex section (e.g. to Annex I) since it deals with the establishment of interfaces with core provisions from other Directives, and it would be best if the new provision was at the same "hierarchical level" of legal systematics. The new provision could also be tacked onto Article 13 that deals with the basic risk management obligations of substance stewards. There are two problems with this solution, however. First, manufacturers and importers, rather than government authorities, would be in charge of enforcement, although pursuant to the provisions of REACH it seems (at least to the present authors) that industry actors are already required to ensure that PNEC limit values are not exceeded in their sphere of competency. The second disadvantage is that the basic obligations of substance stewards under REACH are scattered across the Regulation, i.e. Article 13 pertains to manufacturers and importers, Article 34 pertains to downstream users, and additional basic obligations are found in the various Annexes.

- The PNEC values developed during the risk assessment process under REACH (pursuant to Article 4 ff, as well as Articles 13 and 34 in combination with the provisions in the Annexes)[193] should be used as indicators of compliance with the provisions of the IPPC Directive pertaining to environmental quality standards (Article 10), significant pollution (Article 13(2)), and Community quality standards (Article 10(3)). This same mechanism should be implemented for the PNEC limit values defined under the Existing Substances Regulation.
- The Agency (and, until the Agency is established, the Commission) should publish these values in a suitable form and venue. It also might be advisable to elaborate special procedural rules that would require, for example, the participation of scientific or other committees that could analyze the validity of the actions taken and formulate internal administrative opinions.
- Mechanisms should be instituted that allow for information exchange between public REACH players and authorities that are responsible for the enforcement of regulations pertaining to industrial installations and environmental media.

Another useful measure might be to incorporate into sectoral Community legislation (most notably the IPPC Directive and Water Framework Directive) cross-references to newly created regulatory interfaces. Such trans-sectoral nexuses are indispensable tools for the correction of regulatory interface deficits. Such regulatory “bridges” will be more effective if they are embedded in regulations for more than one sector. This will also send a clear signal to lawmakers in Member States that their own enforcement legislation for the IPPC Directive and Water Framework Directive must be tailored to the new conditions under REACH. Moreover, since these changes are directly related to REACH, they could all be enacted within the framework of a single legislative process. In fact, the current draft of REACH also contains proposed changes for a series of other Directives.

c)
Formation of opinion within administration

As pointed out above, the dearth of interfaces between regulations pertaining to industrial installations, Existing Substances, and environmental media strikes more than just

[193] The same principle should be applied to health related values as well.

the legislative arena. Therefore, it would be advisable to continue the dialog with the various stakeholders that implement industrial installation and water legislation with a view to determining how willing they are to help elaborate legislative interfaces and the attendant administrative underpinnings.

In this process, it should be borne in mind that the administrative procedures pertaining to industrial installation and water legislation[194] are in any case fraught with conflict and that administration struggles with the classic hindrances to implementation. Looking at them, competent authorities are not overly eager or motivated to implement and enforce additional chemicals regulations. These stakeholders are fearful (albeit for no justifiable reason) that their specific “implementation style” will be undermined if interfaces are established with chemicals regulations that follow a different “inner logic.” Thus it is not difficult to imagine a scenario[195] whereby operators assume that where PNEC limit values have not (yet) been reached, they can be simply “filled up.” This would constitute an attempt to sabotage the air and water emissions goals defined by industrial installation legislation. Moreover, this kind of attitude would surely have a devastating effect on the motivation of competent authorities in that it would appear to destroy their achievements. Thus, it is no surprise that competent authorities are reluctant to participate in efforts to transfer chemicals’ risk into their responsiblitiy.

In defining regulatory interfaces and in the administrative and political dialogue leading up to their elaboration, it should be made clear right from the start that (a) PNEC limit values are to be regarded as a mandatory minimum standard and (b) compliance with this standard (assuming that suitable regulatory interfaces have been implemented) is a necessary but not necessarily sufficient precondition for reducing chemical risk. However, it is difficult to

[194] Another problem in this regard is the necessity of integrating new types of regulations into implementation processes. These regulations include IPPC Directive rules pertaining to multiple environmental media in various river basins, which means that the attendant spheres of administrative responsibility exceed the scope of the IPPC Directive alone.

[195] Such scenarios are in fact already occurring.

predict whether the Community institutions will stay the course to support and implement this policy. It is therefore all the more necessary to incorporate the specific procedural risks of decision making at the EU into the strategic planning.

d)
Existing Substances under REACH

The question arises, in connection with the REACH strategy of shifting responsibility to industry, as to how seriously the various stakeholders take (and will take) the theory and practice of self regulation. A key issue in this regard is whether sufficient incentives result from the concept of self regulation to ensure that emissions reduction goals will actually be met. According to an initial assessment by the rapporteur, additional institutional provisions that exceed the scope of the solution to the legislative and administrative interface problem may be needed in order to successfully enact and implement REACH.

The crucial point here is to keep substance stewards' transaction costs to a minimum, as this would increase the likelihood that risk reduction goals would be achieved and would enhance industry's competitiveness. In addition, institutional conditions should be established that promote realization of the requisite risk reduction measures by the various stakeholders, without incurring high transaction costs.

e)
Interim strategy

According to the rapporteur, the main objectives of the REACH interim strategy should be to carry over the results obtained under the Existing Substances regime to the new legal framework, and to promote transfer to REACH of the expertise that has been acquired to date.

Both of these objectives will be furthered if the Existing Substances committees can continue their work during the 18 month transitional period. In order for this to be achieved, transitional regulations such as those in Article 134 of REACH would have to be modified.

The reduction of point source emissions (see sections H2a-d for our recommendations) should also be dealt with, not only

during the time remaining until REACH comes into force, but beyond this point.

It is highly likely that the attendant environmental permission and monitoring instruments will also play a major role under REACH, if only in the guise of supplementary measures that help public authorities to meet their obligations to reduce chemical risk. In this sense, the importance of such instruments should not be underestimated. Hence, contrary to the view held in some circles, seeking to remedy the interface shortcomings between chemical, industrial installation and environmental media legislation is a worthwhile enterprise.

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J Annex

Tables

The following tables provide background information regarding the regulatory context of the three chemicals discussed in section D. The first two tables pertain to aniline and Toluene :

Table 1 shows the risk reduction measures as defined under the applicable Community chemicals regulations

Table 2 lists the risk reduction options defined in legislation pertaining to the reduction of point source emissions

The columns contain the names of the relevant regulations for purposes of comparison.

Table 3 shows the risk reduction options as defined in the chemicals regulations for Navy Blue.

Table 4 summarizes the findings of the case studies of Toluene, Aniline and Navy Blue.

Table 1: Risk Reduction Measures according to current Chemicals Regulation

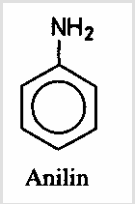
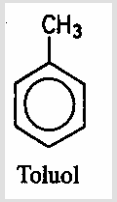
Substance is covered by	*1* ***Directive 67/548/EEC[1]*** ***(Classification and Labelling)***	*2* ***Regulation 793/93 EEC[2]*** ***(Existing Substance Regulation)***	*3* ***Priorisation: Art.8 of Existing Substance Regulation***	*4* ***Directive 769/76 EEC[3]*** ***(Restrictions)***
		If listed in EINECS[4] and one of the conditions of Art.3 is met[5] →		If KOM decides acc. to Art.11 Abs.3 793/93/EWG based on the RAR and the recommendation acc to Sect. 2 that measures are necessary
 CAS 62-53-3	**Classification:** Carc. Cat.3: (i.e. substances, that cause concern for man owing carcinogenic effects but in respect of which the available information is not adequate for making satisfactory assessment.) R 40: limited evidence of a carcinogenic effect. R 68: Irreversibler Schaden möglich. T; R 48 / 23/24/25: toxic: Danger of serious damage to health by prolonged exposure by oral, dermal contact and inhalation N; R50: very toxic to aquatic organism. R 43: may cause sensitisation by skin contact. R 41:Risk of serious damage to eyes.	EINECS No.: 200-539-3 listed in Annex I	**First priority list** **(EC) No 1179/94** **of 25 May 1994** **Rapporteur = D** OJ No. L 131, 26/05/1994 p. 0003 - 0004	Use restriction of the main derivative Methylenedianiline (MDA) acc. to Directive 2003/3/EC from 6. January 2003 on restrictions on marketing and use of the „blue colorant“ (12. amendment of Dir. 76/769/EEC)
 CAS 108-88-3	**Still valid Classification:** F; R11: highly flammable. Xn; R20:harmful by inhalation. **Proposed New Classification:** F; R11: highly flammable. Xn; R38: irritating to skin. R48/20: Danger of serious damage to health by prolonged exposure through inhalation. R63 (Repr. Cat. 3): possible risk of harm to the unborn child. R 65: harmful: may cause lung damage if swallowed R 67: vapours may cause drowsiness and dizziness.	EINECS No.: 203-625-9 listed in Annex I	**second priority l** **(EC) No 2268/95** **of 27 September 1995** **Rapporteur= DK** OJ No. L 231, 28/09/1995 p. 0018 - 0019	Proposal of the Kommission KOM(2004) 320 final. May not be marketed as a substance or as part of a preparation if mass concentration exceeds 0,1% **in consumer adhesive and sprays** placed on the market or used.

Table 2: Risk Reduction Measures according to point specific Legislation

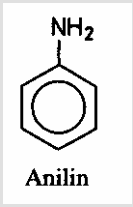
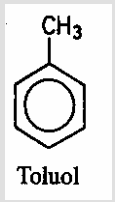
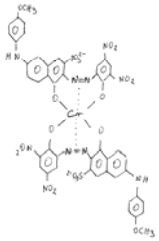
Substance is	*1* IPPC[6]	*2* VOC-Dir[7]	*3* WFD[8]
 CAS 62-53-3	Covered by - Annex I Cat.4.1d (Aniline = containing nitrogen Hydrocarbon, Amine). ➔ production of Aniline is subject to the general provisions acc. to Art.3 - Annex III air No.4 (Aniline = volatile organic compound) ➔ plant permission has to include emissions limits acc. to Art. 9 sect.3 for this dangerous substance	volatile organic compound acc. to Art.2 No.17 ➔ is subject to Art.1 - concerning following activities acc. to Annex I o processing of cautchouc o production of pharmaceuticals - that exceed limits of solvent usage acc. to Annex II A o processing of cautchouc 15 t/a (No.18) o production of pharmaceuticals 50 t/a (No.20) including the national measures that result from national implementation of this Directive	- not listed in Annex X[9] BUT: - might be listed in Annex VIII No.4 because Classification as Carc. Cat.3 , R50 ggf.[10]. If admission in Annex X succeeds: ➔ proposal of Kommission to emission limits acc. to Art.16 sec.6 ff.
 CAS 108-88-3	Covered by - Annex I Cat.1.2 because raw material is crude oil AND - Annex I Cat.1.4 concerning processing ➔ production and processing are subject to general provisions of Art.3 - Annex III air No.4 (Toluol = volatile organic compound) ➔ plant permission has to include emissions limits acc. to Art. 9 sect.3 for this dangerous substance	volatile organic compound acc. to Art.2 No.17 ➔ is subject to Art.1 - concerning following activities acc. to Annex I o adhesive coating o print - that exceed limits of solvent usage acc. to Annex II A o print max. 30 t/a (No.1 ff) o adhesive coating 5 t/a (No.16) including the national measures that result from national implementation of this Directive.	- Not listed in Annex X[11] BUT: - Might be summarized under Annex VIII No 4 acc. to new classification R48 and R63. If admission in Annex X succeeds: ➔ proposal of Kommission to emission limits acc. to Art.16 sec.6 ff.

Table 3: Risk Reduction Measures according to current chemicals regulation and plant specific legislation for the New Substance Navy Blue

Substance is subject of	*Directive 79/831/EEC (6. Adaptiont of Directive 67/548/EEC)*		*Directive 93/67/EEC*[12]	*Directive 769/76 EEC*[13]
 **NAVY BLUE**	R 43: sensitization by skin contact possible[a]. N; R 50-53: very toxic for aquatic organism, may cause long-term adverse effects in the aquatic environment	ELINCS[b] No.: 405-665-4	Risk assessment acc. to. Art.3 sect.4: **conclusion iv)** The substance causes concern and the competent authority shall immediately give recommendations for risk reduction➔	A general restriction of marketing and use is intended[14].

Substance is subject of	**IPPC**[15]	**VOC-RL**[16]	**WRRL**[17] **= WFD**[18]
NAVY BLUE	Subject to - Annex I Cat.6.2 (installations to dye textiles and fibres with a capacity of more than 10 t / d) ➔ if this thresholds is met, dying with Navy Blue is subject to the general provisions of Art.3	**Low volatile compound →** **Is not subject to this Directive**	- Not listed in Annex X[19] BUT: - Might be listed in Annex VIII No.4 because of Classification as N, R50-53. - Contains Chrome = metal compound ➔ Might be listed in Annex VIII No.7

[a] English language version of the 7th edition of ELINCS, draft[a]. (http://ecb.jrc.it/new-chemicals/), 16.05.2004; „no legal status. Neither the Commission of the European Communities nor any person acting on behalf of the Commission is responsible for the use, which might be made of the following information".
[b] European List of Notified Chemical Substances.

Table 4: Overview of the evaluation of the three exemplary substances

	Anilin	Toluol	Navy Blue
risk assessment	Very toxic to aquatic organism, might cause cancer, HVPC; risk to the aquatic environment at least at 7 point sources	HPVC that is emitted in High volume into the air, shows possible risk of harm to the unborn child and danger of serious damage to health by prolonged exposure through inhalation.	Very toxic for aquatic organism, contains chrome, Azo colorant (New Substance) used to dye textile in SME, main pathway into the environment is waste water.
measures			
Chemicals law	Classification and Labelling beyond others R 40, R 50, R 68.	Actual Classification and Labelling R 11, R 20.	Classification and Labelling R 50, R 53, R 43.
IPPC	Art.3 on production and use → MS ensure that no relevant environmental pollution are caused and BAT are used	Art.3 on production and use → MS ensure that no relevant environmental pollution are caused and BAT are used.	Art.3 on use, but only in installations with a capacity > 10 t / d; since application takes place primarily in SME the exceeding of the threshold is rather unlikely.
VOC	- Limit values for applications in cautchouc processing and pharmaceutials production - classification as R40, feed back to the Existing Substances Regime (Art.5 XIII)	- limit values for applications in printing or adhesive coating - no feed back to the Existing Substances Regime, since no class. as R 40, R 60 or R 61	Navy Blue ≠ VOC
WFD	if applicable. Annex VIII No. 4, hitherto (-)	if applicable. Annex VIII No. 4, hitherto (-)	Annex VIII No.7 → Annex II 1.4
Existing Substances Regime	- <u>RAR and CSTEE</u>: No sufficient data to evaluate Toxicity / carcinogenic properties→ further tests - <u>RRS (D):</u> ELVs/EQSs iRv IPPC, WFD, national meas.	- <u>RRS (DK):</u> measures under D 76/464/EEC and IPPC (BREF), perhaps WFD - <u>Kommission:</u> Candidate for Annex X WFD Restriction of use	- conclusion iv) - restriction of use as dye in textiles and leather products acc. to D 2003/3/EC
gap	- although subject to in depth assessment not enough data - unclear responsibility of the necessitiy for harmonized European measures	- short time successes are only probable by restrictions - proposal does not cover the dominant risk sources and minimize the risk of diffuse sources (long term. exp.by inhalation)	- problem to identify the . substance in different provisions - Structure and properties of the compound of two components are unclear

[1] Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances *(OJ L 030 02.02.1985 p. 33)*.
[2] Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances. *Official Journal No L 084, 05/04/1993, p. 0001-0075.*
[3] Council Regulation 76/769/EWG of 27. 07. on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations *(OJ L 262 27.09.1976 p. 201)*
[4] European Inventory of Existing Commercial Chemical Substances.
[5] If the substance itself or in a preparation is produced or put on the market at least once within the last three years before this regulation was put into force and /or after in amounts of more than 1 000 Ton/a
[6] Council Directive 96/61/EC of 24 September 1996 concerning **i**ntegrated **p**ollution **p**revention and **c**ontrol (*OJ L 257, 10/10/1996, P. 26*).
[7] Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations *(OJ L 085 29.03.1999 p. 1)* ("**v**olatile **o**rganic **c**ompounds")
[8] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ("**w**ater **f**ramework **d**irective") (*OJ L 327, 22/12/2000, P. 1*).
[9] Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC *(OJ L 331 15.12.2001 p.1)*
[10] Substance that is proved to own harmful properties to the reproductive functions of the endocrine system in the aquatic environment
[11] Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC *(OJ L 331 15.12.2001 p. 1)*
[12] Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC *(OJ L 227 08.09.1993 p. 9)*
[13] Council Regulation 76/769/EEC of 27. 07. 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations *(OJ L 262 27.09.1976 p. 201)*.
[14] Commission Directive 2003/3/EC of 6. January 2003 on restrictions on the marketing and use of the "blue colorant" (12 Amendment of Council Directive 76/769/EEC on the approximation to the technical progress)
[15] Council Directive 96/61/EC of 24 September 1996 concerning **i**ntegrated **p**ollution **p**revention and **c**ontrol (OJ L 257, 10/10/1996, P. 0026 – 0040).
[16] Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations *(OJ L 085 29.03.1999 p. 1)* ("**v**olatile **o**rganic **c**ompounds").
[17] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy *(OJ L 327 22.12.2000 p. 1)* („**W**ater**F**ramework**D**irective") - (Abl. L 327 v. 22.12.2000, p. 1.
[18] Directive 2000/60/EC of the European Parliament and of the Council of 23. 10. 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22/12/2000, *P. 1*).
[19] Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC *(OJ L 331 15.12.2001 p. 1)*