Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH*

Lars Koch and Nicholas A. Ashford

Abstract

This article analyzes the role of different kinds of information for minimizing or eliminating the risks due to the production, use, and disposal of chemical substances and contrasts it with present and planned (informational) regulation in the United States and the European Union, respectively. Some commentators who are disillusioned with regulatory approaches have argued that informational tools should supplant mandatory regulatory measures unflatteringly described as "command and control." Critics of this reformist view are concerned with the lack of technology-innovation forcing that results from informational policies alone. We argue that informational tools can be made more technology inducing – and thus more oriented towards environmental innovations – than they are under current practices, with or without complementary regulatory mechanisms, although a combination of approaches may yield the best results.

The conventional approach to chemicals policy envisions a sequential process that includes three steps of (1) producing or collecting risk-relevant information, (2) performing a risk assessment or characterization, followed by (3) risk management practices, often driven by regulation. We argue that such a sequential process is too static, or linear, and spends too many resources on searching for, or generating information about present hazards, in comparison to searching for, and generating information related to safer alternatives which include input substitution, final product reformulation, and/or process changes. These pollution prevention or cleaner technology approaches are generally acknowledged to be superior to pollution control. We argue that the production of risk information necessary for risk assessment, on the one hand, and the search for safer alternatives on the other hand, should be approached simultaneously in two parallel quests. Overcoming deficits in hazard-related information and knowledge about risk reduction alternatives must take place in a more synchronized manner than is currently being practiced. This parallel approach blurs the alleged bright line between risk assessment and risk management, but reflects more closely how regulatory agencies actually approach the regulation of chemicals.

These theoretical considerations are interpreted in the context of existing and planned informational tools in the United States and the European Union, respectively. The current political debate in the European Union concerned with reforming chemicals policy and implementing the REACH (Registration, Evaluation and Authorization of Chemicals) system is focused on improving the production and assessment of risk information with regard to existing chemicals, although it also contains some interesting risk management elements. To some extent, REACH mirrors the approach taken in the U.S. under the Toxics Substances Control Act (TSCA) of 1976. TSCA turned out not to be effectively implemented and provides lessons that should be relevant to REACH. In this context, we discuss the opportunities and limits of existing and planned informational tools for achieving risk reduction.

* Reprinted, with minor modifications, from "Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH", Lars Koch and Nicholas A. Ashford, Journal of Cleaner Production 14(1): 31-46, 2006. Copyright (2006), with permission from Elsevier.

1 Introduction

Chemicals are ubiquitous in manifold applications of our daily life. They have different properties and fulfil a wide range of functions. However, apart from their intended purposes, many chemicals also have unintended adverse consequences for human health and the environment. Thus, the production, use and disposal of chemical substances are accompanied by "negative externalities," expressed as human and environmental risks. These risks legitimate and sometimes require government action to ensure human and environmental protection. For risk management purposes, basic information is needed about hazards and exposures to potentially harmful substances. The acquisition of sufficient knowledge concerning negative effects is necessary to assess and manage risks. Adequate means are also required to force producers and manufacturers to reduce risks in a cost-effective way by adopting or developing better safety measures that improve the production process or substitute less- or non-hazardous substances by safer alternatives.

Due to the existence of externalities of chemical production, use, and disposal, informational tools alone, without complementary remediating measures, are not expected to achieve an internalization of these adverse effects by the firms.[25] Often, additional needed regulatory measures are not likely to be created or enforced, and informational tools[26] can at most only partially mitigate the problems connected with chemicals hazards and risks (See Case 2001). We focus here on the role of different types of information in chemicals policy as either precedent and complementary to regulatory policy -- or to economic-based incentives-- or as a self-standing policy.

1.1 Types of Information

In considering the effects of information on risk reduction, it is necessary to distinguish between different types of information. The risk management process conventionally includes the three sequential steps of (1) producing or collecting risk-relevant information, (2) performing a risk assess-

[25] In the special case where only the buyer/user of a product is affected by the hazards of contained substances, informational asymmetries may exist between seller and buyer, but external effects may be absent. In this case, it has been argued that informational tools can theoretically compensate market failures without additional regulatory measures.

[26] Informational tools have been described as "the third wave" of environmental policy, following command-and-control and market-based instruments.

ment, followed by (3) risk management practices. The first two steps are necessary to overcome the problem of informational deficits, whereas the third step of risk management refers to the mitigation of the external effects in terms of hazards and risks.[27]

Categories of information, which are useful in terms of this process, are *scientific* information, *technological* information, and *legal* information (See Ashford and Caldart 1996, p. 311). *Scientific* information encompasses (1) product ingredients and the specific composition of pollution in air, water, soil, and waste, (2) the inherent toxicity and safety hazard of the related chemicals, materials, and industrial processes, and (3) information related to exposure of various vulnerable groups to harmful substances and processes. *Technological* information includes (1) monitoring technologies, (2) options for controlling or preventing pollution, waste, and chemical accidents, and (3) available substitute inputs, final products, and processes. *Legal* information refers to notification of the informational and other rights and obligations of producers, employers, consumers, workers, and the general public. Though important, legal information is not a fundamental *type* of information, but rather the (mandated) diffusion of information about rights and duties stemming from the nature and exposure profiles of hazardous substances and processes, and options for their control.

All types of information are potentially helpful in identifying and reducing the risk of hazardous substances. Knowing the costs, time horizons to acquire information, and asymmetries in accessing or holding of information by government[28], it is important to focus on the diminishing marginal utility of using resources to acquire more information of each type. Moreover, industry and other stakeholders are all important participants in determining how effective different (information) policies might be expected to be in reducing health and environmental risks. Therefore, the application and usefulness of different kinds of information in different stages of the risk management process will be considered.

1.2 The risk management process and problems with a sequential process

Scientific information basically refers to the two steps of production and assessment of information concerning the identity of, and exposure to, hazards. Production and assessment of risk information is costly and time-consuming. Furthermore, there are information asymmetries between firms and government, as well as among other stakeholders, because the producing firms are generally acknowledged to have easier access to risk information of substances that they produce. Thus it is useful and commonplace to require the necessary information from the producing firms. Were it not for mandatory requirements, the firms would have disincentives to produce as well as to diffuse information about hazards and risks, because this could endanger their production opportunities and sales – even though those potentially exposed expect those substances to be safe.[29] The correctness and completeness of risk information produced by the firms correlate directly with the capacity of the government or other stakeholders to audit the information. This process is influenced by two considerations: firstly, it is important to construct regulatory informational measures in such a way that accurate and complete risk information is produced and disclosed. Secondly, the testing requirements for the firms should not unnecessarily burden the production of substances due to the associated costs of producing those data.

The process of producing risk information is embodied in risk assessment: "a way of ordering, structuring and interpreting existing information with the aim of creating a qualitatively new type of information, namely estimations on the likelihood (or probability) of the occurrence of adverse effects" (Heyvaert 1999, p. 135). Risk assessment involves four steps:[30]

- hazard identification
- dose-response assessment
- exposure assessment
- risk characterization

Within the first two steps, existing hazards (e.g., toxicity, flammability, etc.) of a substance are analyzed and the quantitative relationship between different levels of exposure and health/environmental effects are determined. The Probable No-Effect Concentration (PNEC) (i.e., the no-effect threshold) or No Observed Adverse Effect Level (NOAEL) for different exposure pathways and media are identified. However, the relation between dose and (hazardous) response is not easy to determine. Furthermore, tests for effects on hu-

[27] With regard to the large amount of existing chemicals which have not been adequately tested, an additional step of priority setting ranked by expected severity is useful. Different ways of priority setting, as well as their advantages and disadvantages, will not be discussed in this paper, but see Ashford (2000).

[28] For a detailed analysis with regard to the problems of generating and distributing risk information see Gawel 1997.

[29] To the extent that regulatory requirements impose a responsibility to disseminate risk-relevant information, rather than to generate information, the resulting disincentive to produce useful information could have serious consequences. See Ashford and Caldart, 1996, Chapter 7.

[30] See National Academy of Sciences 1983.

mans are conducted on animals, which often react differently to the same exposure (See Heyvaert 1999, p. 139). Moreover, it is difficult to assess the effects of low exposures over a long period of time. This often cannot be simulated by animal testing with high exposures over a shorter period. Therefore, long-term and chronic effects often cannot be accurately predicted. Thus, the data are usually highly uncertain vis-à-vis human health risks.[31]

Exposure assessment refers to the (temporal) description of the amount and concentration of a substance that is released to different media over time by production, use and disposal and that leads to human and environmental exposure and uptake. From this, the Predicted Environmental Concentration (PEC) and biologically-relevant dose (BRD) are determined. In general, a comprehensive exposure assessment is hardly possible. The final step of risk characterization relates the PNEC to the PEC and BRD, to determine whether—and to what extent--the exposure exceeds the thresholds of different pathways of exposure and biological action. In this case, risk assessment may be followed by risk management, a process that heroically assumes that a bright line can be drawn between the assessment of risk and the decision whether and to what extent to reduce (i.e., manage) that risk.

However, quantitative risk assessment presents major challenges and is – depending on the tests required for risk assessment for several endpoints – costly and time-consuming as well. Due to the arguments mentioned above, a comprehensive risk assessment is problematic. Thus, uncertainty vis-à-vis hazards and risks of substances often cannot be easily overcome by more risk information and risk assessment. It is also questionable whether better future science can reduce uncertainty sufficiently and thereby create a more certain basis for risk management.[32] Uncertainty will also be aggravated by the problem of not adequately accounting for possible combined effects/interactions between different substances. In contrast, an initial rough estimation of potential risks is often possible, based on readily-available fundamental information about certain properties of chemicals. In this case, the analysis of quantitative structure-activity relationships (SARs) of substances gains significance, because the information is readily available, is far less expensive, and is predictive of potential hazardousness of substances to some extent.[33]

It should be noted that due to the character of information, its value often cannot be known before having the information. It cannot be determined in advance whether – or to what extent -- additional testing significantly increases the knowledge of safety or lack of safety of a substance and thus creates a better decision basis for the risk management process. In general, the more risk information that is required, the longer and more costly the risk assessment is, and the longer it takes before risk reduction measures can be implemented. However, a comprehensive risk assessment is often required in European and American law before regulatory action limiting the production, use, or disposal of the product is justified. But the collection of these data neither reduces risks *per se* nor stimulates technological innovation. *Thus, we argue that an overly comprehensive and protracted risk assessment process may unjustifiably postpone the implementation of desirable risk reduction measures.*

1.3 Making the case for a more balanced and synchronized process

Relevant to the consideration of the timing – or the right moment – for undertaking risk reduction measures are two types of risk management errors one might make. A Type I error occurs when a substance is regulated which later on turns out to be either not hazardous or less hazardous than expected, whereas a Type II error occur when a suspected hazardous substance is not regulated and it turns out to be hazardous or more hazardous than

[31] See also Gusman et al. 1980, p. 79 concerning the uncertainty of the data.

[32] This statement reflects the inherent limitations of risk assessment. Of course, conducting toxicological or epidemiological studies where there are little or no prior data does reduce uncertainty to a point. See Ashford 2005, 2nd page.

[33] See, for example, OECD 1993. In the 1970's, with the beginning of mandatory regulation in the U.S., for example under the Clean Air Act and the Occupational Safety and Health Act, knowledge about structure activity relationships – i.e., the relationship between chemical structure and toxic action – was limited. Substituting a chemical, for which little actual toxicity/epidemiological data existed, for a known toxic material was very risky. Thirty-five years later, we have accumulated a great deal of experience and our confidence about clearly safer substitutes is much more soundly-based. Our chances of unfortunate surprises are probably greatly diminished. A recent U.S. Government Accounting Office report stresses the increasing importance of SARs (see U.S. GAO 2005). The report observes: "...EPA predicts potential exposure levels and toxicity of new chemicals by using scientific models and by comparing them with chemicals with similar molecular structures (analogues) for which toxicity information is available...EPA believes that the models are generally useful as screening tools for identifying potentially harmful chemicals...EPA believes that, based on limited validation studies, its models are more likely to identify a false positive...than a false negative..." OECD member countries are currently leading collaborative efforts to develop and harmonize SAR methods for assessing chemical hazards. One further consideration is that our technological options are far more varied than "drop-in" chemical substitutes. Alternative synthetic pathways – the focus of "green chemistry" and "green engineering" -- allow us to alter inputs, change final products, and use different production methods that eliminate or drastically reduce the probability of harmful chemical releases and exposures (See Allen and Shonnard 2002; Anastas and Warner 2000; and Ashford and Zwetsloot 1999).

expected (Ashford 2005; VanDoren 1999). Undertaking a comprehensive risk assessment (and delaying in taking a risk management decision) could substantially minimize Type I errors, whereas risk management at an early stage of knowledge about potential risks minimizes the likelihood of Type II errors.[34]

The avoidance of Type II errors also embodies the precautionary principle. One formulation of the precautionary principle is as follows: "Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[35] Thus, essential conditions for applying the precautionary principle are uncertainty and irreversibility.[36] In contrast, avoidance of Type I errors presupposes that a substance is safe, until the opposite has been shown.

Obviously, the relative merits of making a decision between avoiding a Type I error or a Type II error reflects a present trade-off based on currently limited knowledge of the risks of both currently-used technology and alternative technologies and can hardly be based on strictly quantitatively-rational criteria. The regulatory authorities in the European Union and in the United States historically have acted to avoid Type I as well as Type II errors. The industrial producers of chemicals are more concerned with avoiding Type I errors, especially with regard to existing chemicals. In this context, a central question to consider is whether it is possible to decrease the probability of Type II errors, without significantly increasing Type I errors by appropriate information-enhancing activities. In this regard, we argue that, on the one hand a rough *comparative* risk estimation of potential hazards of *alternative technologies (inputs, final products, or processes)* to the technology presenting the putative hazard under scrutiny is possible with relatively low-cost information-enhancing activities, while, on the other hand, a comprehensive and costly risk assessment of the putative hazard alone often does not significantly increase the certainty about risks. Note that *comparative* assessments do not need to entail protracted risk assessments, but rather a comparision of alternatives against currently-used technologies. Thus, we argue later that imposing a requirement for comparative analyses on the proponents of a particular technology is not necessarily a burdensome one.

1.4 Risk management

"[Risk management] attempts to develop a suitable response to a hazard, taking into account all relevant regulatory, political, environmental, engineering and social factors which might be relevant."[37] Risk management is based on a described scientific risk assessment as well as upon a socio-economic assessment of alternative measures to reduce risks. The socio-economic risk assessment is incorporated into a special case of cost-benefit-analysis and is termed risk-benefit analysis.[38] Within these analyses, all relevant costs and benefits of a risk reduction measure are accounted for – starting from a baseline without any regulatory action – and converted into a single unit (usually money) for comparison of both benefits and costs. The consideration between risks and costs for risk reduction is combined with several normative decisions within present tradeoffs. There is no inherently unique value of risk reduction, but it is always determined by political and societal weighting. What is supposed to be a reasonable or unreasonable risk – or an "acceptable risk" -- reflects a normative basis. By converting several costs and benefits into a single unit, different normative decisions must be made, e.g., evaluating environmental and health damages and choosing an adequate discount rate for future damages. By taking only the social costs and benefits into account, distributional effects are often not considered. The assumptions that are taken for compensating remaining uncertainties with regard to risks and costs are also of great importance. The problems of risk-benefit studies in general and arguments for using instead trade-off-analysis, which leaves all costs and benefits in their original units as well as considers the distribution of costs and benefits and thus does not obscure the present trade-offs of risk reduction measures, are comprehensively discussed elsewhere by one of the authors (see Ashford 2000, p. 70; Ashford 2005).

What we emphasize here, instead, is the significance of examining or obtaining information about the expected costs and risks of risk reduction measures (risk control/reduction technologies, as well as safer alternatives) (see Ashford 2005, p. 5). When hazards are expected to exist, it is useful to force the search for safer alternatives *at an early stage* of the process, instead of undertaking a comprehensive

[34] See for example EEA 2001.

[35] Principle 15 of the Declaration of the 1992 UN Conference on Environment and Development (the Rio Declaration).

[36] For an extension of the criteria for the application of the precautionary principle see also Ashford 2005.

[37] See The Physical and Theoretical Chemistry Laboratory, Oxford University, England: Chemical Safety Information – Glossary: http://ptcl.chem.ox.ac.uk/MSDS/glossary/GLOSSARY.html

[38] Whereas the United States has a tradition of applying cost-benefit analysis before implementing regulatory measures, in Europe the discussion about a stronger application of cost-benefit approaches is a more recent and increasingly recommended practice.

risk assessment process first.[39] This implies a change from performing an extensive risk assessment of the putatively hazardous substance to undertaking at an early stage, a *comparative* risk assessment *of known risks* of other substances and processes known to be characterized by recognized safer options *and known costs*[40] for their application. This process involves a synchronized and iterative process involving the three steps of risk information production, risk assessment and the selection of risk management options. To illustrate this, different scenarios can be distinguished:

The present substance is either *known to be safe* or *known to be unsafe in a well-characterized manner*:

This causes neither a problem with a sequential nor with a more synchronized approach.

The present substance is *known to be unsafe* but lacking in important details/characterization:

In this case, following a sequential process creates cost and time problems. Instead of analyzing the lack of safety in detail, it may be more useful to start a comparative socio-economic risk assessment. Whether to explore alternative solutions depends on the costs and benefits (risk advantages) of various control options, including but not limited to input or final product substitution. On the risk side, if the risks associated with the existing alternatives are uncertain, a determination must be made of whether to undertake a process to (1) further clarify the risks of the original substance/chemical, (2) clarify the risks of the existing alternatives *or* (3) instead to search for (or design) clearly-safer alternatives. On the cost side, if control or risk reduction is expensive, it may be very useful – and cost saving – to search for alternatives, preferably – but not necessarily -- at considerably cheaper costs that controlling the original hazard. The necessity for shifting the information activities away from expanding our knowledge about risk– and towards elucidating risk reduction measures and search for information about safer alternatives and subsequent application of known alternatives – depends on the societal cost-benefit calculus of the values of different kinds of information. Simply put, the strategic question becomes one of whether risk of the original substance/chemical or existing alternatives should be further clarified, or new technical options should be explored instead. Even if shifting to an alternative technology (substitute inputs/final products or process changes) is more expensive, its adoption could be justified because of the greater certainty of lower risks from clearly safer substitutes.

The hazardous nature of the present substance is *uncertain:*

In this case it is necessary to specify the kind and extent of the uncertainty. Starting from the properties of a substance, an assessment of the hazardous potential of a substance is fundamental. If a substance contains hazardous potential, a synchronized process of further risk assessment, and comparative risk and cost analyses of substitute technologies, as described under scenario (2) above is useful.

Comparative cost and risk assessments in this discussion thus means a rough assessment of costs and risk between (1) continuing present production (or starting production), and (2) pursuing future alternatives. Due to the uncertainties associated with scientific risk assessment, the socio-economic-risk assessment could involve even more uncertainties where not only the risks are uncertain, but so are the costs and effects of risk reduction measures.

Given that no Type I error (i.e., regulating a clearly non-hazardous substance) was [yet] made, and assuming that new products or processes that are *expected* to be safer will be developed/identified and applied by the firms, two types of error can occur in adopting substitute technologies. First, the new technology could turn out to be no safer -- or even more hazardous than the former one -- (an environmental risk error), and secondly the new technology is not able to fulfil the same functionality (a technological function error). The substitution of presently existing products and processes therefore could create both future technological and environmental risks. In practice, this could stifle their substitution for hazardous substances. Developing and implementing alternative products and processes could be a difficult process. Both incurring the costs of substitution and introducing new risks remain problems. However, depending on the nature of the uncertainties of the risks, undertaking comparative risk assessments on substitutes could be easier (and certainly less controversial) in some cases. For example, the substitutes could create smaller toxicological risks, or equivalent toxicological risks, but not flammability risks associated with the original substance/chemical.

Finally, a conventional sequential risk management process postpones risk management measures, but

---

39 The REACH proposal envisions that EU member regulators will consider alternatives only *after* substances are determined not to be "adequately controlled", and the burden of demonstrating the existence and efficacy of alternatives is on the regulators, not the producer, although the proponents of substitutes are invited to make their case.

40 If the safer alternatives are in existence or use, even if in a minority of cases, costs will be known. If the safer alternatives still need to be developed, it could be argued that they could be of unknown cost or likely to be expensive. History, however, shows that regulations that force the development of new technologies are 3 to 5 times cheaper than industry alleges (U.S. OTA 1995) and that technology-forcing leads to many opportunities to modernize production processes that often yields cost and other savings (Ashford et al. 1985; Porter and van der Linden 1995a and 1995b). Here, too, absolute cost estimates are not necessary, but rather comparative cost analysis.

sometimes not by significantly decreasing uncertainty with regard to the risks of chemical substances. Therefore, it is useful to establish the steps of the risk management process in a more synchronized way. Instead of first doing a comprehensive risk assessment of existing chemicals, it may be more reasonable to start the process of comparative risk assessment and risk management earlier and thus encourage the development and adoption of safer (and cheaper) alternatives. Thus, when hazards are expected to exist, the focus does not lie exclusively in revealing all present hazards of a substance, but creating knowledge about future alternatives. This means a shift of focus from scientific information to technological options information.

Unlike a hazard, risk, or technology assessment, technology options analysis seeks to identify *where and what superior technologies could be adopted* to eliminate the possibility, or to dramatically reduce the probability, of pollution and accidental releases[41]. Ashford (2005) explains:

In order to facilitate pollution prevention or the shift to cleaner technologies, options for technological change must be articulated and evaluated according to multivariate criteria, including economic, environmental and health/safety factors...[T]rade-off analysis ... can be used to document the aspects of the different technology options and, further, it can be used to compare improvements that each option might offer over existing technological solutions. The identification of these options and their comparison against the technology in use is what constitutes Technology Options Analysis (TOA). Hornstein (1992) points out that "it is against the range of possible solutions that the economist analyzes the efficiency of existing risk levels" and that "to fashion government programs based on a comparison of existing preferences can artificially dampen the decision makers' actual preference for changes were government only creative enough to develop alternative solutions to problems" (Hornstein 1992).

At first blush, it might appear that TOA is nothing more than a collection of multivariate impact assessments for existing industrial technology and alternative options. However, it is possible to bypass extensive cost, environmental, health and safety, and other analyses or modelling by performing *comparative analyses* of these factors (such as comparative technological performance and relative risk and ecological assessment). Comparative analyses are much easier to do than analyses requiring absolute quantification of variables, are likely to be less sensitive to initial assumptions than, for example, cost-benefit analysis, and will enable easier identification of win-win options. Thus, while encompassing a greater number of technological options than simple technology assessment (TA), the actual analysis would be easier and probably more believable.

TOAs can identify technologies used in a majority of firms that might be *diffused* into greater use, or technologies that might be *transferred* from one industrial sector to another. In addition, opportunities for technology development (i.e., innovation) can be identified. Government might merely require the firms or industries to undertake a TOA. On the other hand, government might either "force" or assist in the adoption or development of new technologies. If government takes on the role of merely assessing (through TA) new technologies that industry itself decided to put forward, it may miss the opportunity to encourage superior technological options. Only by requiring firms to undertake TOAs, or undertaking TOAs itself, is government likely to facilitate major technological change. Both industry and government have to be sufficiently technologically literate to ensure that the TOAs are sophisticated and comprehensive.

Encouraging technological change may have payoffs, not only with regard to environmental goals, but also to energy, workplace safety, and other such goals (see Ashford and Heaton 1983). Because many different options might be undertaken, the payoffs are somewhat open-ended. Hence, looking to prioritize different problem areas cannot be the same kind of exercise as a risk-assessment-based approach. A fraction of the amount of money devoted to a single animal study could instead yield some rather sophisticated knowledge concerning what kinds of technology options exist or are likely in the future. Expert technical talent in engineering design and product development (through green chemistry or green engineering) can no doubt produce valuable information and identify fruitful areas for investment in technology development (Anastas and Warner 2000; Allen and Shonnard 2002).

1.5 Informational tools for an orientation towards safer alternatives

For reaching a more synchronized risk management process, risk reduction measures are needed which

[41] A risk assessment, in practice, is generally limited to an evaluation of the risks associated with the firm's established production technology and does not include the identification or consideration of alternative production technologies that may be environmentally-sounder or inherently-safer than the ones currently being employed. Consequently, risk assessments tend to emphasize pollution control or secondary accident prevention and mitigation strategies, which impose engineering and administrative controls on an existing production technology, rather than primary prevention strategies, which utilize input substitution and process redesign to modify a production technology. In contrast to a risk assessment, a technology options analysis would expand the evaluation to include alternative production technologies and would facilitate the development of primary pollution and accident prevention strategies.

push firms efforts towards the search for safer alternatives at an early stage. Where regulatory tools are not implemented or enforceable, it is useful to explore the limits and opportunities of informational tools. As discussed earlier, informational tools can be based on the three types of information – scientific, technological and legal information – with different effects. Questioning the importance of scientific information as a precondition for risk management measures has been discussed above in detail. The availability and the assessment of scientific information alone does not reduce risks, without complementary risk-reduction measures. Thus, informational tools useful for risk management should be based on technological information as well. This mainly includes:

Requirements for firms to disclose risk information to the public. Here, the disclosure refers to the exposure profiles of produced substances and to their toxicity, flammability etc. Information disclosure creates the opportunity for the public to react and avoid exposure to existing hazards and risks by e.g., changing consumer behaviour or applying pressure on firms. These can be effective parts of the risk management process, without making risk reduction measures obligatory for the firms[42]. Information regulation can help lessen the need for more formal regulatory risk-reduction requirements. Information disclosure can *motivate* firms to search for safer alternatives by public or market pressure[43]. The effectiveness of information disclosure depends on the informational value for different stakeholders, and their reaction on the information. This is discussed later in the context of the Toxic Release Inventory in the United States.

Requirements for the firms to identify and generate technological options to reduce existing risks. This informational requirement obligates firms to go beyond reporting what they have done in the past to reduce risks. A more far-reaching requirement is to require the firms to focus on future options for developing and implementing safer alternatives. This can take place e.g., by having the firm undertake a technological options analysis. By being required to think about alternatives, firms increase their *capacities* to undertake changes[44].

Complementary informational tools include databases of preferred and disfavoured technologies, as well as labels for safe or hazardous products (or processes). "Negative" lists can increase the pressure on firms, that use these substances (analogous to (1)), whereas positive lists increase their capacity to substitute hazardous substances or processes (analogous to (2)). Although important as well, these tools will not be discussed here.

2 The Legal Frameworks in the United States and the European Union

In the first section of this article, it was argued that implementing risk management practices at an early stage, instead of trying first to overcome the existing lack of information concerning the riskiness of chemical substances/processes, could be a more productive approach. Achieving risk management goals using informational tools has been suggested where regulatory measures are not implemented or are not likely to be enforced. Therefore, it is useful to distinguish different informational tools vis-a-vis their potential to strengthen risk management. This section describes the strengths and weaknesses of the legal frameworks in the United States and the European Union, focussing on informational requirements to collect data on chemical substances as well as to implement risk reduction measures[45]. Due to the fact that the restriction or ban of substances is used only very rarely – although more often in the European Union than in the United States – we will argue that alternative informational tools could compensate for the lack of stringent regulatory risk reduction measures.[46]

While in the United States, as well as in the European Union, regulations creating testing obligations for new chemicals[47] were implemented in the seventies, no routine tests were required for chemicals which were already on the market– the so called "existing chemicals". The vast majority of the substances on the market – over 90 % – are existing substances (Warhurst 2005, p. 11). Therefore, the different ways of data collection and risk management especially with regard to the existing chemicals will be highlighted here[48], although the United States and the European Union also differ in their legal frameworks for new chemicals. Due to the fact that European directives have to be implemented

42 See Karkkainen 2001.

43 It has been suggested that increased requirements for risk assessment under REACH may have this effect. See later discussion.

44 See later discussion in sections 2.4 and 2.5 of the effectiveness for stimulating technological change of different reporting requirements that divulge cleaner production/pollution prevention practices.

45 See U.S. GAO 2005 for a comparison of U.S. EU, and Canadian approaches to testing chemicals.

46 Here we do not focus on laws that regulate hazardous emissions to water, air and waste etc., although these laws are also helpful for reducing the production, consumption and disposal of hazardous substances.

47 These regulations refer to chemicals, which were not regulated under other acts such as pesticides, nuclear material, food additives, drugs, cosmetics, alcohol and tobacco.

48 There also exist many programs on the national as well as international level to overcome the lack of knowledge with regard to existing chemicals – most of them voluntary – which are not considered here.

into the national legal frameworks, there are also differences between the member states. Notwithstanding these differences, the description here occasionally refers to the German implementation of European law.

2.1 Legal Framework in the EU

The current legal framework for new chemicals in the European union is based on the 6th amendment (issued in 1979) of the Council Directive 67/548/EEC. Those substances, produced before 1981 had to be registered in the European Inventory of Existing Commercial Chemical Substances (EINECS) without any further testing obligations. EINECS contains 100,106 entries. The latest data from the European Commission's Joint Research Centre (Pedersen et al., 2003) indicates that the numbers of substances in the different tonnage categories are as follows:

- 1-10 t/a (tonnes per annum) – 17,500 substances
- 10-100 t/a – 4977 substances
- 100-1000 t/a – 2641 substances
- >1000 t/a – 7204 substances [High Production Volume Chemicals]

Within the implementation of the directive in Germany, there was also codified the legal possibility for the authorities to require tests for existing chemicals, in case of supposed hazards. This legal possibility was never applied. Instead there was chosen a cooperative way to work up the information deficit with regard to existing chemicals, which will not be discussed here.[49] The other EU member states mostly abandoned work on this problem until the promulgation of a joint regulation in 1993. The unequal treatment of new and existing chemicals is considered as having a negative impact on the innovation of new chemicals. This is due to the testing costs for new chemicals, which increases the incentive to find new applications for existing chemicals instead of inventing and registering new (and safer) ones.

In 1993, the European Union implemented the Existing Substances Regulation (EC Regulation 93/793) to overcome the lack of knowledge with regard to the properties (hazards) and uses of existing chemicals. The regulation required some producers, manufacturers and importers to present a base data set for existing chemicals. The deadline for substances produced or used in amounts greater than 1000 tons/year was March 23, 1994 and for amounts greater than 10 tons/year June 4, 1998. On the basis of the data, the European Commission developed four priority lists, which include 141 existing high-volume chemicals. For each chemical a member state was chosen to be responsible for the risk assessment including risk management proposals, on basis of all available data within the firms about hazards and exposition. Afterwards, the proposals of the member states have to be discussed on the European level and changed where required, until all member states agree with it (Stirba/Kowalski/Schlottmann 2001, p. 60). Since there were only few incentives for the firms to provide risk information – and due to the extensive regulatory procedure of risk assessment – so far only 70 risk assessment reports have been finished (European Chemicals Bureau [ECB] Newsletter 1/2005).[50] The risk assessment reports end up with one of the following conclusions for each report.

There is need for further information and/ or testing.

There is at present no need for further information and/ or testing or for risk reduction measures beyond those which are being applied.

There is need for limiting the risks: risk reduction measures which are already being applied shall be taken into account.

These conclusions are different for risks for workers and consumers, and are different for health effects in general and environment.

Warhurst (2005) provides an assessment of the data on high production volume (HPV) substances:

In 1999 the ECB analyzed the data it had received from industry on the properties of their HPV chemicals (Allanou et al., 1999). This study found that:

- Only 14% of the EU High Production Volume Chemicals had datapublicly available at the level of the base-set;
- 65% had some data but less than base-set;
- 21% had no data.

Without this data it was impossible to assess which chemicals were a priority for further evaluation in the existing chemicals program, and unclear how industry was managing to carry out its other responsibilities, such as classification and labelling chemicals and assessing risks to workers. As a result of these studies a Swedish government official stated, "*most substances on the market are in reality not covered by the current legislation*" (EU Chemicals Regulators, 1999).

The risk assessment reports offer a basis for risk reduction measures, but they give no advice about how to reduce risks. An evaluation of the regulation

[49] For a detailed analysis of this cooperative committee, see Koch 2006.

[50] Indeed for 127 substances, there already exists a first draft Risk Assessment Report.

shows that for 34 out of 41 chemicals the reports conclude with either (i) or (iii). Vis-à-vis workers, the reports conclude in 70% of the cases that further risk reduction measures are needed (Bodar et al. 2003, p. 1041). Comparing the supposed risks, which led to the setting on the priority list, with the found risks, underestimations have been approximately three times more often than instances of overestimations. Thus, the Type 1 errors – not regulating a hazardous substance – has been significantly higher than Type 2 errors – regulating a non-hazardous substance. This strengthens the argument for adopting risk reduction measures at an earlier stage of knowledge in the conducting of risk assessment.

The Legal basis for restrictions of new as well as existing chemicals is the Council Directive 76/769/EEC, as transposed into the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. Whereas the data collection and assessment takes place under the authority of the EU Environmental Directorate, the implementation of restrictions is under the authority of the EU Internal Market Directorate. As a consequence, the information collected by the first directorate is only partly used as a basis for actions with regard to market restrictions. As a result, most of the few procedures for market restrictions within the European Union are not initiated by the European Commission, but by a single member state.

In turn, the possibilities for national risk reduction measures are restricted due to the European legal framework. Before a national implementation, initiatives for market restrictions have to be reported to the European Commission. This can be a long process, especially, if the Commission decides to aim at restrictions on the European level. For these reasons, market restrictions for chemical substances were a very rarely used instrument on the national, as well as on the European level.

2.2 Registration, Evaluation and Authorization of Chemicals – REACH

Since Regulation 93/793 could not resolve the information deficit because of the slow risk assessment process[51], the European Commission developed proposals for a new regulation, which were published in 2003.[52] The political process started with the publication of the whitepaper in 2001 focusing on strategies for a future chemicals policy. The new system is called REACH – Registration, Evaluation and Authorization of Chemicals.[53] The main elements are uniform procedures of registration and evaluation for new and existing chemicals in place until 2012 and the transfer of responsibility for producing and assessing data to the industry, as well as the expansion of responsibilities to the downstream users. As for new chemicals, the required data set depends on the amount produced annually. Generally the system is three-tiered. All chemicals produced in higher amounts than 1 t/y have to be registered without any further evaluation (ca. 30,000 substances). A safety assessment report is necessary for substances produced in amounts over 10 t/y (ca. 15,000 substances). This report contains not only data about substances' properties and exposure profiles, but also data about necessary risk reduction measures that need to be taken to assure safe application/use from the producer through to the downstream users. A safety data sheet, that also contains information about necessary risk reduction measures has to be passed onto, and if necessary modified, within the actors in the supply chain.[54] All substances produced in higher amounts than 100 t/y (ca. 10, 000 substances) and the substances which are produced in lower amounts, but are suspected to be hazardous, will be evaluated by the authorities after registration (ca. 5000 substances).[55]

In contrast to the well-defined data requirements for risk assessment, the responsibility for risk management is defined only cursorily and superficially in REACH (Art. 13, 6)

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 function of this risk management element in REACH highly depends on clear definition of "adequate control" and sanctions for non-compliance. The point of reference for adequate control seems to be the determination and shortfall of the Probable No-Effect Concentration (PNEC) for the environment and the Derived No-Effect Level (DNEL) for human health.[56] But so far, the consequences and

51 The failure of Regulation 93/793 has been analysed and discussed in both scientific and political contexts. For the former, see Winter et al. (1999) and Winter (2000); for the latter, see European Commission (1998).

52 See European Commission (2003) and (2004)

53 See European Commission (2001)

54 In the proposal of the first reading in the European Parliament and the Council, the requirements for tests for low volume chemicals (1-10 tons) were relaxed by creating exemptions for substances which do not have certain properties and no relevant exposures.

55 The authorities have to evaluate the underlying test plan of an enterprise for a substance, whereas other evaluations like completeness and quality of the registration dossier are optional.

56 See REACH, Annex I.

sanctions[57] for an exceeding of the PNEC respectively DNEL are not quite clear.[58] Moreover due to the negative incentives for the enterprises to identify risks, control mechanism and sanctions for inadequate registration dossiers are also important and so far very limited.

Chemicals with certain hazardous properties must be separately authorized. This includes substances which can cause cancer or mutations or are toxic to reproduction (the so called CMR-substances), or are either persistent, bio-accumulative and toxic (PBT), or very persistent and very bio-accumulative (vPvB). For these substances the burden of proof shifts from the authorities to the producers, who are now in charge to demonstrate the safety of a substance to get the authorization. The authorization in turn does not automatically take place for all, but only for safe applications. In the latest version of the draft law, an authorization (for production and use) is possible, if the risks of an application can be "adequately controlled" or if the producer is able to prove, that the socio-economic benefit exceeds the risks.[59] These conditions create wide discretion for the authorities. In the first reading of the proposal in the European parliament and the Council, two different suggestions were made to strengthen the substitution principle in the authorization system. Whereas the European Parliament does not want to grant an authorization if safer alternatives are available, the Council does not go that far, and it suggested that the applicants would only have to demonstrate that they have checked safer alternatives before an authorization is granted. So far, it is not clear which form the final regulation will have.

The main motivation in revising the European chemicals policy is the past failure in mitigating the information deficit with regard to the existing chemicals. Despite the planned changes of the new system, this approach basically follows the path of first solving the risk information problem, before risk management can take place. Nevertheless due to the shift of responsibility for the risk assessment to the industry this system is argued to be more feasible than the existing regulation. Moreover the testing demands are more flexible in comparison to the existing regulation that demands a very comprehensive risk assessment. Identifying risk reduction measures is also integrated into the responsibility of the producers and users of chemical substances. But so far, this responsibility is described only very vaguely in contrast to the detailed requirements of reporting data about risk information. To guarantee, that the system of controlled self-responsibility of industry with regard to risk management works, it must be accompanied by adequate control mechanisms and sanctions. Otherwise, REACH will collect data about risk information without significantly forcing or encouraging risk reduction measures.

In principle, the Authorization system could establish a new form of (regulatory) risk management, on the basis of the reversal of the burden of proof for substances with certain properties. The system can be seen as the embodiment of the precautionary principle, because substances are to be screened for their possible potential effects and not only because risk has been scientifically validated. How this system will work, depends on the form and application of this system by the authorities, but the system has come under criticism (Warhurst 2004 and 2005). The wide discretion within the authorization system contains the danger of not making use of the potentially available precautionary approach in REACH. As past experience shows, discretion has often weakened the application of a regulation in practice (see also section 2.3). Thus, to ensure the application of the precautionary principle, it is important to strengthen its requirements in the authorization process. To strengthen the substitution principle – as suggested above – is movement in the right direction.

2.3 Toxic Substances Control Act (TSCA)

In the United States the Toxic Substances Control Act was passed in 1976 and confers the Environmental Protection Agency (EPA) manifold rights to require testing or reporting activities for new and existing chemicals and to regulate them.[60]. The main goals of TSCA are receiving adequate data about the negative effects of chemical substances and regulating such substances, which present or will present an "unreasonable risk of injury to health or the environment"[61]. Negative impacts for the economy and innovation should be avoided by

[57] In REACH, Titel XIII sanctions are defined very vaguely.

[58] Apart from the authorization system, the legal opportunities to restrict the marketing and use of a substance by the authorities where essentially adopted from the existing regulatory framework (see REACH, Title VIII).

[59] However, a decision based on the socio-economic benefit has also to take into account existing safer alternatives. See REACH, Art. 57, 3.

[60] See Ashford and Caldart 1996, 193ff

[61] In the early implementation years of TSCA (1976-1980), EPA adopted a risk-driven approach to existing chemicals by constructing different classes of chemicals based on production volume and toxicity. This was seen as a logical necessary first step on the way to efficient regulation. This allegedly "rational" approach, which consumed most of the resources of the EPA Office of Toxic Substances, left little agency resources for actually promulgating regulations. This ultimately led to an essential failure of TSCA to live up to expectations. A "death blow" was delivered in 1991 by the Fifth Circuit Court of Appeals in rejecting EPA's attempt to ban asbestos, perhaps the most notorious and well-acknowledged carcinogenic chemical substance in commerce (see footnote 36).

using the "least burdensome [regulatory] requirements".

For new chemicals, a Premarket Manufacturing Notice (PMN) is required. Thereupon EPA decides on a case-by-case basis if more tests are necessary, but most often no new testing was required. Existing chemicals are registered in the "Inventory of Chemical Substances (ICS)", the US equivalent to EINECS. In contrast to the European union, where different inventories for new and existing chemicals exist, the new substances are added to the ICS after the Premarket Manufacturing Notice (PMN) as well. The ICS contains some 75,000 existing substances (Ginzky 1999, p.153).

Under TSCA, testing for existing chemicals is required by the establishment of testing rules for as many as 50 chemicals per year following recommendations by the Interagency Testing Committee (ITC). On this basis EPA requires tests from industry or EPA has to justify why tests from their point of view are not necessary. In practice, a relatively small number of those rules were actually promulgated. In the first 15 years of TSCA, the ITC proposed tests for 175 chemicals to EPA, but EPA thereupon required testing from industry for only 25 chemicals. For 34 other chemicals EPA and industry agreed on voluntary testing, and for 8 other chemicals, tests were only proposed (Walker 1993). In contrast to the European attempts to improve the legal framework for existing chemicals, TSCA has not changed substantially in this regard since its first implementation. However, in the late 1990s, EPA did implement its High Production Volume (HPV) Challenge Program under which chemical companies have begun to voluntarily provide test data on 2800 chemicals produced in amounts greater than 1 million pounds per year, although they have not agreed to testing 300 of the chemicals originally on the HPV list (U.S. GAO 2005).

TSCA also requires the firms to deliver new information about hazards of the produced substances to EPA. EPA has to be notified of "significant new uses" of registered chemicals, as well. It is within the administrative discretion of EPA to determine what constitutes significant new uses. Along the lines of German/European law, EPA has also the right to require a toxicity analysis of existing chemicals, if an "unreasonable risk" is supposed. The basis for risk reduction measures in TSCA is the existence of an unreasonable risk. It is not the intention of TSCA to prevent any risk, but to take into account the benefits as well as risks of a substance. In fact, only few chemicals are restricted by TSCA. Within the first 20 years of the passage of TSCA, limitations were determined for only 17 substances (Walker, 1993, p. 185). As of 2005, only five chemicals or classes of chemicals: polychlorinated biphenyls, fully halogenated chlorofluoroalkanes, dioxin, asbestos[62] and hexavalent chromium were restricted or banned comprehensively. In conclusion, although the opportunities for the authorities available to EPA under TSCA are very comprehensive, EPA essentially did not use the variety of available options for requiring data and for minimizing risks in the past. TSCA could truly be described as a "paper tiger." Given the broad regulatory discretion of EU under REACH, there is a legitimate concern that – although containing different risk management elements – it could suffer a similar fate.

2.4 The Toxic Release Inventory (TRI)

In addition to the testing rules for existing chemicals, there are other mechanisms which focus on the public disclosure of hazardous expositions in terms of releases, mainly represented by the Toxics Release Inventory (TRI). TRI is part of the federal Emergency Planning and Community Right-to-Know Act (EPCRA), which was established in 1986.[63] The implementation of EPCRA can be seen as a reaction of the chemical accident in Bhopal, India, where several thousand people were killed and hundred of thousands were injured due to releases of methyl isocyanate. The main purpose of EPCRA "is to inform communities and citizens of

[62] The regulation for asbestos was nullified by the Fifth Circuit Court of Appeals [*Corrosion Proof Fittings v. EPA* 947 F.2d 1201 (5th Cir.1991)]. TSCA requires EPA to consider, along with the toxic effects on human health and the environment, "the benefits of such substance[s] and mixture[s] and the *availability* of substitutes for such uses...(emphasis added)" Because EPA did not explore regulatory options other than a ban, and more specifically, because EPA did not evaluate the toxicity (and costs) of likely substitute products in a search for "least burdensome requirements", the court vacated the proposed standard and remanded it to EPA for further proceedings. While arguably the court incorrectly interpreted TSCA's requirements as to mandating substitutes' toxicity (and cost) comparisons – and could have sought the regulation in another circuit court to give a more favorable result – the EPA chose not to attempt to reinstate the asbestos ban, primarily because of the likely extensive burden on agency resources to perform extensive risk and economic assessments for substitutes. For all intents and purposes, EPA regards TSCA as a "dead letter". There is a danger that REACH suffer the same fate, with the result that regulation (authorization and restrictions) are not often vigorously pursed. Note, as discussed earlier, that *comparative* assessment of risks and costs are not nearly as burdensome as conducting separate risk and cost assessments. Whether using comparative assessment could circumvent the hurdle EPA needs to overcome to satisfy the requirements laid out in *Corrosion Proof Fittings* needs to be explored. Because the issue of alternatives needs to be considered in formulating regulations under TSCA, this may well be possible. In contrast, because risk assessment seems to drive the REACH process, and because the consideration of alternatives seems to come in later, whether the use of comparative analysis in the context of REACH can circumvent the need for extensive risk analyses is unclear.

[63] The reporting requirements for TRI can be found in EPCRA, section 313. Apart from TRI, EPCRA also includes three other legislative parts: emergency planning, emergency release notification, and hazardous chemical storage reporting requirements. See Environmental Protection Agency (EPA): http://www.epa.gov/tri/

chemical hazards in their areas." EPCRA requires certain industries to announce the releases and transfers of certain chemical substances to air, water, land or transferred off-site. The data have to be brought in via a standardized form and are collected by the Environmental Protection Agency (EPA) in the Toxics Release Inventory (TRI) which is publicly available.[64] The amount of chemicals which are covered has meanwhile doubled since 1987 to about 650 chemicals.

TRI covers firms that have more than 10 employees and that produce, manufacture or import over 25,000 pounds per year, or use 10,000 pounds per year of these chemicals. For some persistent, bioaccumulative and toxic chemicals (PBT) EPA lowered the reporting thresholds in 1999 to 100 pounds, for highly persistent and highly bioaccumulative chemicals to 10 pounds and for dioxin and dioxin-like compounds to 0.1 gram (EPA 2003, p. 1). All facilities of the manufacturing sector and several other industries are required to deliver data, thus 6100 facilities are charged to report their releases. Altogether, approximately 6-7 % of all chemical releases are subject of TRI. Apart from the reporting requirements for chemicals releases, EPCRA itself does not include any other regulatory measures. [65] The costs of complying with TRI mainly consist in the working hours needed within the firms to provide the data. These costs amount about $475 million a year. For the role for PBT-substances in 2000 the costs are estimated with $147 million in the first reporting year 2000, and $81.6 in the subsequent years.[66] These costs do not include further indirect costs of TRI for the firms. The administration costs for EPA are estimated as relatively low.

Our assessment of TRI mainly focuses on two issues: (1) whether the TRI-data represent a good indicator of firms' environmental performance, and (2) whether the TRI-data were treated as if they were a good indicator of firms' environmental performance, revealed by the firms' direct reaction as well as to reactions of other stakeholders that resulted in a change of the firms' behaviour.

2.4.1 Limits of TRI:

The purpose of TRI is to overcome part of the information deficit with regard to the present hazards of chemicals by informing the public. The potential power of TRI depends on quality and quantity of the data, as well as the capacity of the public to understand and interpret the data. More available information does not necessarily mean increased knowledge. "If information is not provided in a clear and useable form, it may actually make people less knowledgeable than they were before, producing over-reactions, or under-reactions, based on an [in]ability to understand what the information actually means (Sunstein 1999, p. 626)."

First considering the quantity of existing chemicals that are covered, TRI focuses only on the releases of chemicals from manufacturing plants and does not include the whole life cycle of a product. Moreover, only 6-7 % of all releases are covered. A reported reduction in chemical releases does not necessarily mean a total reduction of releases but could also be a result of shifts in releases from covered to not covered chemicals. Since there is little knowledge vis-à-vis the existing chemicals, it is difficult to estimate whether TRI covers the most hazardous chemicals. Moreover, the firms are not required to produce risk information about the covered substances, but only have to report their releases. In addition, within the covered substances, no difference is made between the different severity (i.e., health or environmental consequences) of releases. With regard to the quality of the data, all hazards of the reported chemicals are equally treated – apart from the recent exception of the persistent, bioaccumulative and toxic chemicals. By only looking on the total amount of releases, the widely varying risks of hazardous substances are not factored in. No matter which releases were reduced, they were all implicitly dealt with as if they were equally hazardous. The total decrease in all releases, can nevertheless increase the releases of more hazardous chemicals and thus increase the total risks (Volokh 2002).

This is also true for different types of releases. A shift from one emission type to another can also cause more problems, although the total amount of releases remains equal or is decreasing. Moreover, TRI does not require a uniform reporting system, and firms are also allowed to change their reporting system in time. Several examples show that a firm can create paper reductions of substances' releases by changing the reporting system, although the releases have not decreased. Thus reported reductions can partly be attributed to changes in reporting methods (Volokh 2002). By taking all these limitations of TRI into account, the potential power of the data is very doubtful. Neither is it clear that all

64 The data can be found on EPA's webpage: http://www.epa.gov/tri/

65 The 1990 Pollution Prevention Act (PPA) represents a stricter movement from pollution control to pollution prevention. The PPA augments EPCRA and adds further requirements related to pollution prevention activities to industrial reporting. . Firms are asked to report source reduction activities they are undertaking and additional data about their waste management practices. The list of substances required to be reported as "releases" has also been expanded. Very few pollution prevention activities have in fact resulted from the PPA requirements.

66 See Subcommittee on Regulatory Reform and Oversight 2002, p. 9.

relevant releases are covered, nor that the reduction of reported releases also means a real decrease of releases on the one hand and a decrease of risks due to hazards on the other hand.

2.4.2 Effects of TRI

Although there are limitations to consider the TRI-data as a good environmental indicator, the publication of the data appeared to have an enormous positive impact on the reduction of reported releases. During the period from 1988-2001 on- and off-site releases of the core chemicals were reduced by 54,5 % while the production increased. 39.6% of the decrease were already reached by 1995 (Environmental Protection Agency (EPA) 2003). Actually while emissions to air and water decreased, there were corresponding increases in hazardous waste. Due to the fact, that hazardous waste may be more problematic than the decreased emissions, the success of TRI is far from clear.

According to EPA, the TRI-data are widely used by the industry itself, the government, communities, public interest groups, the stock market, insurance companies, consultants, etc. (EPA 2003). The data are used to evaluate and improve firms' environmental performance, to set pressure on firms, to localize further regulatory call for action, to educate the public about hazards in their neighbourhoods, etc. Due to the fact that the firms are only required to report their releases without any further regulatory requirements, it is important to explore the factors that have caused the (reported) reductions. Konar and Cohen (1996) show in their study, that the stock market reacts on unexpected high releases of firms within the first publication of TRI-data in 1989 with abnormal stock value decreases. This does not mean that the worst performing facilities also experienced the highest stock decreases, because the stock market could have expected that in advance because of reports in the media and therefore has already reacted (Konar and Cohen 2003, p. 13). But all of the firms with abnormal stock decreases were in the upper third of polluting firms. These firms with the worst stock market reaction, thereupon decreased their TRI-releases significantly to a larger extent than the average performing firms. Thus it can be concluded that the stock market incorporates and evaluates TRI-data as an indicator for environmental performance or for the efficiency of firms. Firms with high releases are supposed to be vulnerable with regard to costs to comply with potential future environmental regulations or are considered not to be organized efficiently. As a reaction, these firms have a higher incentive to improve their TRI-performance for being better evaluated by the stock market. It is not clear if this is more than a one-time effect with an expected decreasing significance in time.

Furthermore, the representation of workers in environmental management within firms plays an important role. The more worker representatives are involved in firms' decisions, the more the firms tend to reduce the reported releases (See Bunge et al. 1996, p. 9). In contrast, there are no empirical findings for a significant influence of the public to push firms in decreasing their releases (See Oberholzer-Gee and Mitsunari 2002). However, this could be also due to the difficulties in measuring this correlation.

2.5 The Massachusetts Toxics Use Reduction Act (TURA)

The Massachusetts Toxics Use Reduction Act (TURA) was passed in 1989 with the goal to reduce the use of hazardous substances by 50 % by 1997 (Massachusetts Toxics Use Reduction Institute (TURI) 1997, p.1-1). "TURA is a "planning tool" for more efficient industrial operations that would produce less waste" (TURI 2004). It requires facilities to report their releases of toxic substances along the lines of EPCRA. But under TURA over 1,400 chemicals are subject to reporting[67], although only 250 of the listed chemicals are relevant for Massachusetts.[68] Over 1000 facilities took part in the program at the beginning, where today only about 600 are left. The others mostly quit using the reported chemicals (TURI 2004 and Karkkainen 2001).

In contrast to EPCRA, TURA contains also two essential extensions: TURA not only requires data about chemical releases but also about chemical use. Thus, TURA demands a mass balance of toxic substances for the whole production process. Furthermore TURA requires facilities "to undergo a planning process to identify opportunities for toxics use reduction" (TURI 1997, p. 1-1). While EPCRA requires firms to report only what pollution prevention actions they are currently taking, it calls firms to focus on future alternatives by asking not only what they have been doing, but also *what they could do*, to reduce the use and releases of hazardous substances. Firms have to prepare a Toxics Use Reduction Plan to show how toxic chemicals are

[67] All of the substances on the federal Toxics Release Inventory (TRI) under Section 313 of the federal Emergency Planning and Community Right to Know (EPCRA) are regulated. Also, substances found on the federal Comprehensive Environmental Response and Compensation Liability Act (CERCLA) list are subject to TURA reporting and planning, except for chemicals that are delisted.

[68] Other states like New Jersey or Oregon have also implemented similar mandatory programs, but TURA is seen as the most ambitious. See Karkkainen 2001.

used and how they could be reduced within the whole life cycle. (This is the essence of Technology Options Analysis:)

"Each plan must provide a corporate policy statement and two- and five-year goals for by-product reduction of each listed chemical. In addition, each plan must include information about current and projected toxic chemical use, the technical feasibility of implementing various techniques, and the economic impacts of each technique; a description of each technique or procedure that is to be implemented; and a schedule for implementation" (TURI 2004).

Basic toxic use reduction techniques are: input substitution, product reformulation, production unit redesign or modification, production unit modernization and improved operation and maintenance (TURI 2004). The costs of the regulation between 1990 and 1997 have been estimated to be $76.6 Million (including fees the firms have to pay) according to calculations of the Massachusetts Toxics Use Reduction Institute, whereas the benefits only for the firms have been savings of $90.5 Million. This sum does not include environmental and health benefits (See TURI 1997, p. ES-5).

As a result of including the whole production process of toxic substances and focussing on future options, Massachusetts is seen as the most successful state of the United States with regard to reducing use and releases of toxic substances. Comparable success can be found e.g., in New Jersey, where similar regulations took place. Between 1990 and 2000 the reporting facilities have reduced the use of toxic substances by 45 %, by-products and waste per unit of products by 69 % and releases by 92 %. Toxics shipped in products were reduced by 60 % (TURI 2004). Thus the success of TURA in reducing hazardous substances within the whole production process is much more far-reaching than for TRI. Furthermore, firms were able to save money by implementing safer alternatives into the production process, thus the costs of TURA already appear to be exceeded by the benefits.

2.6 TRI and TURA: Opportunities and Limitations

Despite of the limits of the TRI-data, they seem to be widely recognized as an indicator for firms' environmental performance. Thereby especially the stock market and the workers representation have a significant impact on the decrease of the reported firms' releases. Thus, the disclosure of hazardous releases can be a potentially powerful tool. Therefore it seems to be useful to increase the potential power of TRI by improving quantity as well as quality of the data (See for example Tietenberg and Wheeler 1998). With regard to the quantity, TURA shows the way by focusing on the whole production process. Moreover more firms and substances could be subject to TRI.

Improving the quality of the data means, among other things, the distinction between the varying degree of severity of hazardous substances. This is combined with increasing complexity for the processing of the data, as well as the public capacity to interpret the data. "However, too much information can produce cognitive overload and lower the effectiveness of disclosure" (Tietenberg and Wheeler 1998). It is also important for the quality of the data to establish a unique reporting standard. Otherwise firms have an incentive to use the reporting standard to reduce their releases on the paper. Basically it is important to ask whether it is possible to create a comprehensive information system at acceptable costs that adequately measures different environmental performances of firms. Otherwise it could be useful to focus on other measures to reduce risks. Looking at the actual costs of TRI, a further extension of its application to other chemicals may not be as useful as other initiatives.

In contrast, the tools implemented by TURA are inexpensive and also cost-effective for the firms. One of the key success factors of TURA in this regard – apart from the extension of requirements for the delivered data to the whole production process – was the focus on identifying future technological options to reduce hazardous substances. By requiring the firms to make alternatives explicit, it increases firms' capacities to find solutions to reduce risks and safe money at the same time. Thus, TURA seems to be a successful informational tool to encourage risk reduction measures. It is arguable that there are limits to the amount of chemicals a system like TURA is able to handle in this comprehensive manner. However, if one assumes that the total number of chemicals that actually present significant toxic exposures are of the order of a few thousand or less, the TURA approach could well be sufficient.

3 Conclusions

In this paper we argued for a more synchronized risk management process, as well as for the application of informational risk management tools, especially if regulatory risk management measures are not likely to be enforced. Different kinds of information are useful for all stages of risk management. For existing chemicals, there is both a lack of knowledge about hazards (risk) and a lack of regulatory risk reduction measures. In this context, informational tools as a complement of risk management, can be helpful to encourage firms to reduce

risks. Therefore, the simultaneous promotion of firms' public disclosure, on the one hand, and capacity building by drawing their attention to future options, on the other hand, as applied in Massachusetts seems to be a promising approach. In particular, learning from TURA could help to force the planned risk management elements under REACH.

In contrast, the European reorganization of chemicals policy continues to focus on a solution driven mainly by addressing the lack of knowledge about risk with regard to the existing chemicals. The essential failure of TSCA in the United States should awaken the EU authorities to the possibilities of a similar result. Indeed there are some important novel elements of REACH, e.g., the responsibility shift from the authorities to the industry and the integration of identification of risk reduction measures in the safety assessment report; and the authorization system could possibly offer a promising tool with regard to the improvement of risk management, depending on its final form. To be effective, these elements highly depend upon aggressive interpretation and implementation by the EU. If this turns out not to be the case, it is very likely that REACH will mainly result in the collection of data about risk, and the risk-reduction opportunities will remain greatly underutilized.

In finalizing REACH, serious consideration should be given to replacing the sequential process involving the production of risk assessment data and analysis, followed by authorization, by a more synchronized and iterative process. The production of risk information necessary for risk assessment, on the one hand, and the search for safer alternatives on the other hand, should be approached simultaneously in two parallel quests. Overcoming deficits in hazard-related information and knowledge about risk reduction alternatives must take place in a more synchronized manner than is implicit in REACH.

Acknowledgments

The authors are indebted to the following who critiqued earlier versions of this paper: Paul Anastas, Michael Warhurst, Nicolas Sadeleer, and Gerd Winter. The authors, of course, are responsible for the final paper.

References

Allanou R., Hansen, B.G., van der Bilt, Y. (1999): Public availability of data on EU High Production Volume chemicals. Ispra, Italy: ECB. http://ecb.jrc.it/existing-chemicals/PUBLIC_AVAILABILITY_OF_DATA/

Allen, David T. and David R. Shonnard. (2002): "Green Engineering: Environmentally Conscious Design of Chemical Processes." Prentice Hall: Upper Saddle River, NJ.

Anastas, Paul and John Warner (2000): Green Chemistry Theory and Practice, Oxford Unversity Press, Oxford, UK.

Ashford, Nicholas A. (2000): "An Innovation-Based Strategy for a Sustainable Environment", in: Hemmelskamp, Jens, Klaus Rennings, and Fabio Leone, (Eds.): Innovation-oriented Environmental Regulation. Theoretical Approaches and Empirical Analysis, Springer Verlag, Heidelberg, New York, 67-107. Available at http://hdl.handle.net/1721.1/1590

Ashford, Nicholas A. (2005): Implementing the Precautionary Principle: Incorporating Science, Technology, Fairness, and Accountability in Environmental, Health and Safety Decisions, International Journal of Risk Assessment and Management, Inderscience, UK.

Ashford, Nicholas A., Christine Ayers, and Robert Stone. (1985). Using Regulation to Change the Market for Innovation. Harvard Environmental Law Review 9(2), 419-466.

Ashford, Nicholas A., Caldart, Charles C. (1996): Technology, Law and the Working Environment, Island Press: Washington D.C.

Ashford, Nicholas A., Heaton, George R. (1983): Regulation and Technological Innovation in the Chemical Industry, in: Law and Contemporary Problems, 46, 109-157.

Ashford, Nicholas A. and Gerard Zwetsloot (1999): Encouraging Inherently Safer Production in European Firms: A Report from the Field, Journal of Hazardous Materials, Special Issue on Risk Assessment and Environmental Decision Making, A. Amendola and D. Wilkinson (eds.), 1999, pp 123-144. Available at http://hdl.handle.net/1721.1/1582

Bodar, C.W.M, et al (2003): Evaluation of EU Risk Assessments Existing Chemicals (EC Regulation 793/93), in: Chemosphere 53, 2003, 1039-1047.

Bunge, John, Cohen-Rosenthal, Edward, Ruiz-Quintanilla, Antonio (1996): Employee participation in pollution reduction:. preliminary analysis of the Toxics Release Inventory, in: Journal of Cleaner Production 1, 4, 9-16.

Case, David W. (2001): The Law and Economics of Environmental Information as Regulation, in: Environmental Law Reporter, 31, 10773-10789.

EU Chemicals Regulators (1999): Future European Chemicals Policy: Report Brainstorming session 16-17 December 1999. The Netherlands: Ministry of Housing, Spatial Planning and the Environment. http://www.vhcp.nl/actualiteiten/reportbrainstorm.pdf

European Chemicals Bureau (2002): Newsletter 1, 2005, http://ecb.jrc.it/NewsLetter/newsletter200501.pdf.

European Commission (1998): Bericht über die Durchführung der Richtlinie 67/548/EWG, der Richtlinie 88/379/EWG, der Verordnung 793/93 und der Richtlinie 76/769/EWG (Report on the Application of Directive 67/548/EEC, Directive 88/379/EEC, Regulation 793/93 and Directive 76/769/EEC)

European Commission (2001): White Paper – Strategy for a future Chemicals Policy, 88(01).

European Commission – Environment DG (2003): The new chemicals regulation – REACH: http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm, 29.10.2003.

European Commission/Environment Directorate General/Enterprise Directorate General (2004): REACH in Brief, manuscript, 15.09.2004, (16 pages).

European Environmental Agency (2001): Late lessons from early warnings: the precautionary principle 1896-2000. EEA: Copenhagen.

Environmental Protection Agency (2004): Toxic Release Inventory (TRI) Program: http://www.epa.gov/tri/.

Gawel, Erik (1997): Reguliertes Wissen um Unwissen. Zur Generierung und Distribution von Risikoinformation aus ökonomischer Sicht, in: Dieter Hart (Ed.): Privatrecht im „Risikostaat", Baden-Baden, 265-323.

Ginzky, Harald (1999): Nutzen und Kosten im Chemikalienrecht der USA, in: Winter, Gerd/ Ginzky, Harald/ Hansjürgens, Bernd (Ed.): Die Abwägung von Risiken und Kosten der europäischen Chemikalienregulierung. Erich Schmidt Verlag: Berlin.

Gusman, Sam, von Moltke, Konrad, Irwin, Frances, Whitehead, Cynthia (1980): Public Policy for Chemicals. National and International Issues. Conservation Foundation: Washington D.C.

Heyvaert, Veerle (1999): Reconceptualizing Risk Assessment, in: Reciel, 8, 135-143.

Hornstein, David (1992): Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis, Columbia Law Review, Vol. 92, p. 562-633

Jacob, Klaus (1999): Innovationsorientierte Chemikalienpolitik. Politische, soziale und ökonomische Faktoren des verminderten Gebrauchs gefährlicher Stoffe, Herbert Utz-Verlag: München.

Karkkainen, Bradley C. (2001). Information as Environmental Regulation: TRI and Performance Benchmarking, Precursor to a New Paradigm? Georgetown Law Journal 89: 257-370.

Koch, Lars (2006): Kooperative Umweltpolitik: Theoretische Einordnung und empirische Fallstudien, in Koch, Lars/Monßen, Melanie (Hg.): Kooperative

Umweltpolitik und nachhaltige Innovationen – Das Beispiel der chemischen Industrie. Physica-Verlag: Heidelberg, 97-210.

Konar, Shameek, Cohen, Mark A. (1997): Information as Regulation: The Effect of Community Right to Know Laws on Toxic Emissions, in Journal of Environmental Economics and Management 32.

National Academy of Sciences (1983): Risk Assessment in the Federal Government: Managing the Process, National Academy Press, Washington, D.C.

Oberholzer-Gee, Felix, Mitsunari, Miki (2002): Information Regulation: Do the Victims of Externalities Pay Attention? http://wc.wustl.edu/workingpapers/OberholzerGee_Mitsunari.pdf

OECD (1993): Application of Structure-Activity Relationships to the Estimation of Properties Important in Exposure Assessment. OECD Environmental Monograph 67

Pedersen, F., J. de Bruijn, S. Munn, and K. van Leeuwen, (2003): Assessment of additional testing needs under REACH: Effects of (Q)SARS, risk based testing and voluntary industry initiatives. European Commission Joint Research Centre, Institute for Health and Consumer Protection. http://ihcp.jrc.cec.eu.int/DOCUMENTATION/IHCP_Reports/REACH%20testing%20needs%20final.pdf

Porter, M. E., & van der Linde, C. (1995a). Green and Competitive: Ending the Stalemate. Harvard Business Review. September/October 1995, 73:120-134.

Porter, M. E., & van der Linde, C. (1995b) Towards a New Conceptualization of the Environment-Competitiveness Relationship. Journal of Economic Perspectives 9(4), 97-118.

Subcommittee on Regulatory Reform and Oversight (2002): It is Time to Reevaluate the Toxic Release Inventory. The TRI Lead Rule: Costs, Compliance, and Science, 13.06.2002, http://www.mercatus.org/research/RSP19992.htm.

Stirba, Uwe/ Kowalski, Ulrike/ Schlottmann, Ulrich (2001): National Profile. Chemikalienmanagement in Deutschland, http://www.baua.de/amst/amst.htm.

Sunstein, Cass R. (1999): Informational Regulation and Informational Standing: Akins and Beyond, in: University of Pennsylvania Law Review 613.

Tietenberg, Tom, Wheeler, David (1998): Empowering the Community: Information Strategies for Pollution Control. Frontiers of Environmental Economics Conference, October 23-25. http://www.worldbank.org/nipr/work_paper/ecoenv/confpap.pdf.

The Physical and Theoretical Chemistry Laboratory, Oxford University, England (2004): Chemical Safety Information – Glossary: http://ptcl.chem.ox.ac.uk/MSDS/glossary/GLOSSARY.html

TURI = The Massachusetts Toxics Use Reduction Institute (2004) Results to date: http://turadata.turi.org/Success/ResultsToDate.html

U.S. Environmental Protection Agency (2003): 2001 Toxics Release Inventory (TRI). Public Data Release – Executive Summary. http://www.epa.gov/tri/tridata/tri01

U.S. GAO (General Accounting Office). 2005 "Chemcal Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program" June 2005, GAO-05-458.

U.S. OTA (Office of Technology Assessment). 1995. Gauging Control Technology and Regulatory Impacts in Occupational Safety and Health: An Appraisal of OSHA's Analytic Approach. Washington, DC: U.S. Congress, Office of Technology Assessment (OTA-ENV-635); September 1995.

VanDoren, Peter M. (1999): Chemicals, Cancer, and Choices. Risk Reduction through Markets, Cato Institute: Washington D.C.

Volokh, Alexander (2002): The Pitfalls of the Environmental Right-to-Know, in: Utah Law Review 2, 805.

Walker, John D. (1993): The TSCA Interagency Testing Committee, 1977-1992: Creation, Structure, Functions and Contributions. U.S. Environmental Protection Agency: Washington D.C.

Warhurst, A. Michael (2004): The REACH Files: A Policy Guide published by World Wildlife Fund European Policy Office, Brussels, accessible at: http://www.panda.org/downloads/europe/reachfilespolicyguide.pdf

Warhurst, A. Michael (2005): Assessing and managing the hazards and risks of chemicals in the real world – the role of the EU's REACH proposal in future regulation of chemicals, manuscript distributed at the Framing a Future Chemicals Policy: A Working Forum for Stakeholders, Boston 28-29 April 2005 (12 pages), submitted for publication in Environment International, Fall 2005.

Winter, Gerd, Harald Ginzky and Bernd Hansjürgens (Eds.) 1999: Die Abwägung von Risiken und Kosten der europäischen Chemikalienregulierung. Erich Schmidt Verlag: Berlin.

Winter, Gerd (Ed.) (2000): Risk Assessment and Risk Management of Toxic Chemicals in the European Community – Experiences and Reform. Nomos: Baden-Baden.