

# **COMMENTARY ON THE CALIFORNIA SAFER CONSUMER PRODUCT REGULATIONS (and STATEMENT OF REASONS) (dated July 18, 2012)**

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**In general, the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices. While I have made specific suggestions discussed below for changes, the rule is sound.**

## **SECTION 69502.2 CHEMICALS OF CONCERN IDENTIFICATION**

In the Statement of Reasons: Section on Definitions.

Page 11, paragraph 2, line 12: add the words “industrial and agricultural workplaces” after “offices,”

Page 11, paragraph 2, line 15: add an additional bulleted item after the second bullet:

- emissions from office equipment and machines, industrial processes, and the use of chemically-formulated products by workers.

In the regulations:

Page 8, section 69501.1 line 17: (20) ‘Chemical of Concern’ add to line 18 the words: “or identified as a chemical of concern by the European Commission under the REACH initiative”

Page 21, section 69502.2(a)1B, line 30: insert the words: “or identified as a chemical of concern by the European Commission under the REACH initiative” after the word “mutagenicity” AND

Page 21, section 69502.2(a)1C, line 33: insert the words: “or identified as a chemical of concern by the European Commission under the REACH initiative” after the long reference number.

In the Statement of Reasons:

Page 63, lines 31-32: limiting the listing of some of the possible endocrine disrupting chemicals to those produced in amount exceeding 1000 tons per year is unnecessarily permissive. Very low concentrations of endocrine-impacting chemicals pose serious risk, so this large volume trigger in the classification is unjustified on public health grounds.

At line 33, add the following: “This 1,000 ton (2 million pounds) amount could well be reduced to 500,000 pounds and a schedule be included in the regulation that reduces this amount over time. A possible schedule might be:

“Beginning on the date the regulations are finalized, chemicals that are possible endocrine disruptors will be defined as those whose production volume exceeds the following levels:

At 2.5 years: 250,000 pounds

At 5.0 years: 125,000 pounds

At 7.5 years: 50,000 pounds

At 10 years: 25,000 pounds.”

In the regulations:

Page 23, section 69502.2b(4), line 41. Being able to classify as a chemical of concern on the basis of the availability of a safer substitute is extremely important and should be retained. This ties together risk assessment and alternatives assessment. However, I would expand the ‘substitution availability’ to include ‘use of a safer technological or administrative approach that delivers a comparable functional purpose’. The substitution criteria should not be restricted to chemical substitutes. Recommendation: insert the words “safer technological or administrative approach that delivers a comparable, but safer functional purpose or” before the words ‘availability of’ at line 42.

General Remarks: I am generally impressed with the thoroughness and comprehensiveness of the factors to be considered – and data bases used -- in designating a chemical a ‘chemical of concern’. It is particularly gratifying to see that concerns for occupational exposures, sensitive populations, neurotoxicity, endocrine disruption, and developmental effects are reflected in the regulations.

## **SECTION 69503.2 PRIORITY PRODUCTS PRIORITIZATION FACTORS**

In the Statement of Reasons:

Page 89, lines 37-38: *to the extent that information is available*. It ought to be acknowledged that privately-held information will be obtained through appropriate legal vehicles reflected in federal or state *right-to-know* authorities, and through subpoena power if necessary. Restricting the acquisition of information gathering to voluntary submissions is antiquated. At line 41, after the word “information.” ADD: “DTSC will also obtain information through Federal and California right-to-know authorities and, when necessary, through the use of subpoenas and other legal instruments.”

In the Statement of Reasons:

Page 91, 69503.2(a) (1)B4 e: last line: Add underlined words: “These controls are taken into consideration when assessing exposure, it is also recognized that the use of these controls in actual practice may be low.”

General Remarks: Here too, I am generally impressed with the thoroughness and comprehensiveness of the factors to be considered – and data bases used -- in designating a product a ‘priority product’. It is particularly gratifying to see that concerns for occupational exposures, sensitive populations, neurotoxicity, endocrine disruption, and developmental effects are reflected in the regulations.

## **SECTION 69503.5 ALTERNATIVES ANALYSIS THRESHOLD EXEMPTION**

This section could be made much stronger, offering more public health protection if the approach taken in classifying a chemical a ‘chemical of concern’ were also taken in determining whether a threshold exemption for a priority product ought to be available or allowed. In the case of carcinogens, mutagens, teratogens, and endocrine disrupter it is not good enough to be ‘below detectable quantities or concentrations.’ Mentioned above was the comment vis-à-vis classification:

Page 23, section 69502b4, line 42. Being able to classify as a chemical of concern on the basis of the availability of a safer substitute is extremely important and should be retained. This ties together risk assessment and alternatives assessment. However, I would expand the ‘substitution availability’ to include ‘use of a safer technological or administrative approach that delivers a comparable functional purpose’. The substitution criteria should not be restricted to chemical substitutes. Recommendation: insert the words “a safer technological or administrative approach that delivers a comparable, but safer functional purpose or” before the words ‘availability of’ at line 42.

Section 69503.5 should adopt a similar approach. The following text should be added – as a new section 69503.5(f) at page 32, line 30, to the regulation and explained in the statement of reasons:

(f) The threshold exemption will not be available in the case of carcinogens, mutagens, teratogens, and endocrine disrupters if a safer substitute technology – including a technological or administrative approach or a substitute product -- is available and offers reasonably similar functionality.

## **SECTION 69505 ALTERNATIVES ANALYSIS**

### **Section 69505.4 ALTERNATIVES ANALYSIS: Second Stage**

In the regulations:

Page 44-45 of the regulations (section 69505.4 Alternatives Analysis: Second Stage, step 3c) last line p. 44: replace “the alternative” with “the three best alternatives”

In the statement of reasons:

Page 118, line 21: replace “the most suitable alternative” with “the three most suitable alternatives”

Insert the following paragraph before the last paragraph that begins on line 24:

“Note that regulations [section 69505.4 Alternatives Analysis: Second Stage, step 3c] page 45, line 2 speaks of “comparative analysis”. Comparative analyses (for example of toxicity, persistence, etc.) are much easier to do than a full-fledged analysis of each alternative. Asking the applicant/responder to select three alternatives, rather than select a single alternative, allows the Department to make much more sensible regulatory choices that maximize protection of public health and the environment, and further, this change goes a long way towards enabling the Department to make the best choice, than simply a better choice of technologies and approaches.”

## **ADDITIONAL REMARKS REGARDING THE ECONOMIC IMPACT OF THE PROPOSED RULE**

While not asked to comment upon the likely economic impact of the rule, I offer the following remarks.

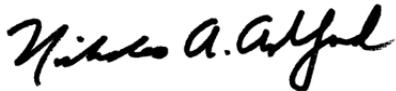
1. The costs of additional tasks imposed upon the proposed rule should be balanced against (1) the public health and environmental consequences of not implementing the rule, and (2) the benefits of stimulating replacement of problematic chemicals (derived from the list of chemicals of concern) by more benign chemicals, changes in reformulated or substitute products, process technology, and other technological and administrative practices.
2. In general, much chemical production and usage has remain static for decades, while new products, synthetic pathways, ad approaches have been the focus of innovation that have insufficiently penetrated the market and general practice. Thus, the proposed rule can properly be interpreted as a ‘modernization of the chemical industry’ [1].
3. There will be winners and losers among industrial actors, but innovation and economic growth crucially depends on industry and product turnover and evolution. Otherwise the industrial sectors and nations in which they are embedded remain static and uncompetitive.

4. Europe and Asia are advancing in chemical innovation, and the chemical industry in the United States cannot afford to lag behind in the development and deployment of environmentally safer chemicals and processes.
5. Finally, the proposed rule advances the regulation of chemicals from an exclusively risk-driven process towards a technology-based process which is less expensive by not requiring detailed and full-fledged risk analysis, and instead fostering *comparative* risk analysis and functional analysis -- and the identification of better technologies and approaches [2].

[1] "Using Regulation to Change the Market for Innovation," N.A. Ashford, C. Ayers, R.F. Stone, *Harvard Environmental Law Review*, Volume 9, Number 2, Summer 1985, pp. 419-466. Available at <http://hdl.handle.net/1721.1/1555>

[2] "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. Available at <http://hdl.handle.net/1721.1/38476> Revised version published in *Environmental Law Network International* 2(2005):22-37. Available at <http://hdl.handle.net/1721.1/55292>

Respectfully submitted,



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## USING REGULATION TO CHANGE THE MARKET FOR INNOVATION\*

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### INTRODUCTION

Technological innovation<sup>1</sup> is both a significant determinant of economic growth and important for reducing health, safety, and environmental hazards. It may be major, involving radical shifts in technology, or incremental, involving adaptation of prior technologies. Technological innovation is different from diffusion, which is the wide-spread adoption of technology already developed.

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1. Technological innovation is the first commercially successful application of a new technical idea. By definition, it occurs in those institutions, primarily private profit-seeking firms, that compete in the marketplace. Innovation should be distinguished from invention, which is the development of a new technical idea, and from diffusion, which is the subsequent widespread adoption of an innovation by those who did not develop it. The distinction between innovation and diffusion is complicated by the fact that innovations can rarely be adopted by new users without modification. When modifications are extensive, the result may be a new innovation. Definitions used in this article draw on a history of several years' work at the Center for Policy Alternatives at the Massachusetts Institute of Technology, beginning with a five-country study: National Support for Science & Technology: An Explanation of the Foreign Experience (Aug. 18, 1975) (CPA No. 75-12). Some definitions appear in that study at pages 1-12.

Several commentators and researchers have investigated the effects of regulation on technological change.<sup>2</sup> Based on this work and experience gained from the history of industrial responses to regulation over the past fifteen years, designers may now be able to fashion regulatory strategies for eliciting the best possible technological response to achieve specific health, safety, or environmental goals. These technological responses to environmental regulation include adoption of compliance technology, change in process technology, and product substitution. In some cases, regulation need only create a climate in which existing technologies, known to produce the desired environmental results, will be adopted or diffused on a large scale. In others, however, the requisite technology may be lacking altogether, and thus regulation must stimulate research and development. Underlying a regulatory strategy based on an assessment of technological options is a rejection of the premise that regulation must achieve a *balance* between environmental integrity and industrial growth, or between job safety and competition in world markets.<sup>3</sup> Rather, such a strategy builds on the thesis that health, safety, and environmental goals can be *co-optimized* with economic growth through technological innovation.

The concept of technological change is the foundation of a regulatory design strategy based on the promotion of innovation.<sup>4</sup>

2. Stewart, *Regulation, Innovation, and Administrative Law: A Conceptual Framework*, 69 CALIF. L. REV. 1259 (1981); Magat, *The Effects of Environmental Regulation on Innovation*, 43 LAW & CONTEMP. PROBS., Winter-Spring 1979, at 4. For a review of prior research at the Center for Policy Alternatives and elsewhere, see Ashford & Heaton, *Regulation and Technological Innovation in the Chemical Industry*, 46 LAW & CONTEMP. PROBS., Summer 1983, at 109.

3. Environmental, health, and safety regulation, as seen by economists, should correct market imperfections by internalizing the social costs of industrial production. Regulation results in a redistribution of the costs and benefits of industrial activity among manufacturers, employers, workers, consumers, and other citizens. Within the traditional economic paradigm, economically efficient solutions reflecting the proper *balance* between costs and benefits of given activities are the major concern.

4. The work of Burton Klein best describes the kind of industry and economic environment in which innovation flourishes. B. KLEIN, *DYNAMIC ECONOMICS* (1977). Klein's work concerns the concept of dynamic efficiency, as opposed to the static economic efficiency of the traditional economic theorists. In a state of static efficiency, resources are used most effectively within a fixed set of alternatives. Dynamic efficiency, in contrast, takes into account a constantly shifting set of alternatives, particularly in the technological realm. Thus, a dynamic economy, industry, or firm is flexible and can respond effectively to a constantly changing external environment.

Several conditions are critical to the achievement of dynamic efficiency. A dynamically efficient firm is open to technological development, has a relatively nonhierarchical structure, possesses a high level of internal and external communication, and shows a

While a new technology may be a more costly method of attaining *current* environmental standards, it may achieve *stricter* standards at less cost than adaptation of existing technology. The following figure illustrates the difference.

Suppose it is determined (by either market demand or regulatory fiat) that a reduction in health risk from point "A" to the

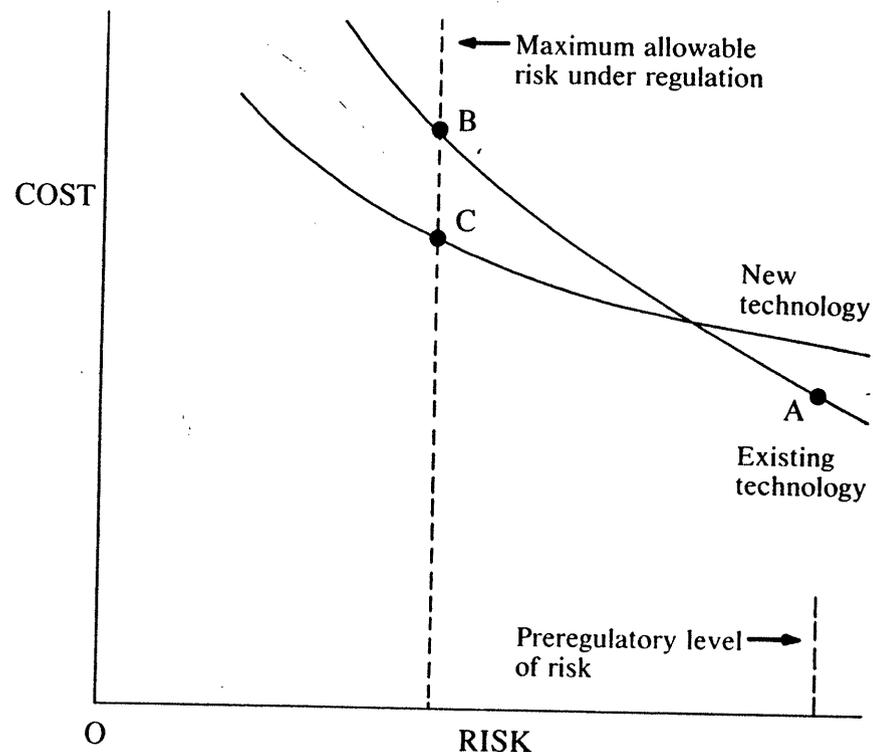


FIGURE 1  
AN INNOVATIVE RESPONSE TO REGULATION

willingness to redefine organizational priorities as new opportunities emerge. Dynamically efficient industry groups are open to new entrants with superior technologies and encourage "rivalrous" behavior among industries already in the sector. In particular, dynamic efficiency flourishes in an environment that is conducive to entrepreneurial risk-taking and does not reward those who adhere to the technological status quo. Thus, Klein emphasizes structuring a macroeconomy containing strong incentives for firms to change, adapt, and redefine the alternatives facing them. Regulation is one of several stimuli which can promote such a restructuring of a firm's market strategy.

dotted line is desirable. Use of existing technological capabilities would impose a cost represented by point "B." However, if it were possible to elicit technological innovation, a new "supply curve" would arise, allowing the same degree of health risk reduction at a lower cost represented by point "C." Alternatively, a greater degree of health protection could be afforded if expenditures equal to costs represented by point "B" were applied instead to new technological solutions. Note that co-optimization resulting in "having your cake and eating it too" can occur because a new *dynamic efficiency* is achieved.

In creating an atmosphere conducive to innovation, a regulator must assess the innovative capacity of the target industrial sector. The target sector may be the regulated industry, the pollution control industry, or a related industry capable of producing substitute technology. The analysis should focus principally on the process of technological *change* within the possible responding sectors. The regulator should analyze a sector's "innovative dynamic" rather than its existing, static technological capability. An assessment of this innovative dynamic requires a historical examination of the pattern of innovation in the regulated industry, an evaluation of the technological capabilities of related sectors having incentives to develop compliance or substitute technology, and a comparison between the regulated sector and analogous sectors with documented technological responses to regulation. The assessment should include an analysis of the industry's existing technological capabilities as well as a reasoned prediction of its innovative potential under the challenge of regulation. This kind of assessment will assist the design of regulations promoting innovation beneficial both to public health and the environment, and to economic growth within the responding industrial sector.

This article will present a model of the effects of regulation on technological change,<sup>5</sup> provide a brief history of environmental regulation affecting innovation,<sup>6</sup> and review innovation waivers under the Clean Air Act, the Clean Water Act, and the Resource Conservation and Recovery Act ("RCRA").<sup>7</sup> Finally, it will discuss

5. See *infra* text accompanying notes 9-33.  
 6. See *infra* text accompanying notes 34-139.  
 7. See *infra* text accompanying notes 140-231.

concerns regarding the design of regulations which do not pit technological innovation against other social concerns.<sup>8</sup>

I. A MODEL OF THE EFFECTS OF REGULATION ON TECHNOLOGICAL CHANGE

Prior work has developed models for explaining the effects of regulation on technological change in the chemical, pharmaceutical, and automobile industries.<sup>9</sup> The schematic below presents a modified model, structured to assist in designing regulations, rather than simply to trace the effects of regulation on innovation.

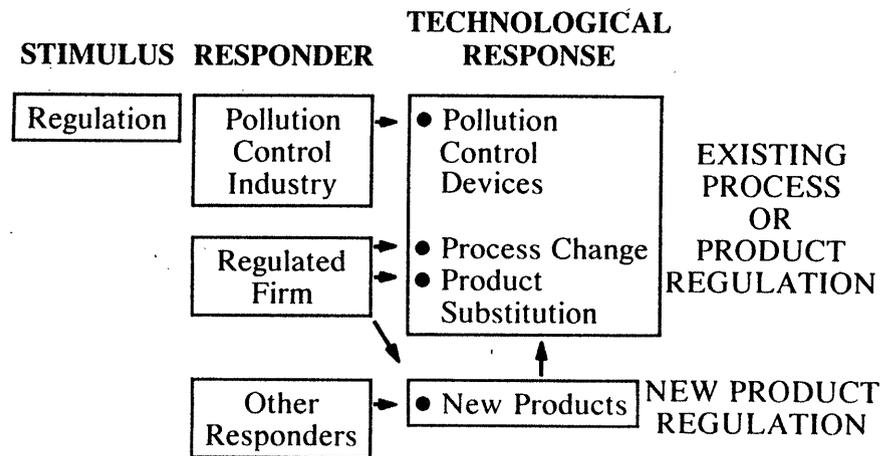


FIGURE 2  
 A MODEL FOR REGULATION-INDUCED TECHNOLOGICAL CHANGE

8. See *infra* text accompanying notes 232-246.  
 9. See Ashford & Heaton, *supra* note 2. See also Ashford, Heaton & Priest, *Environmental, Health, and Safety Regulation and Technological Innovation*, in *TECHNOLOGICAL INNOVATION FOR A DYNAMIC ECONOMY* 161 (1979); Ashford & Heaton, *The Effects of Health and Environmental Regulation on Technological Change in the Chemical Industry: Theory and Evidence*, in *FEDERAL REGULATION AND CHEMICAL INNOVATION* 45 (C. Hill ed. 1979) [hereinafter cited as *FEDERAL REGULATION AND CHEMICAL INNOVATION*].

### A. The Regulatory Stimulus

Environmental, health, and safety regulations affecting the chemical industry include controls on air quality, water quality, solid and hazardous waste, pesticides, food additives, pharmaceuticals, toxic substances, workplace health and safety, and consumer product safety.<sup>10</sup> These regulations control different aspects of development or production, change over time, and are "technology-forcing" to different degrees.<sup>11</sup> Thus, designers of regulations should consider that the effects on technological innovation will differ among regulations which:

- a) require demonstration of product safety prior to marketing (pesticides, food additives, pharmaceuticals, and new chemicals<sup>12</sup>);
- b) require demonstration of the efficacy of products prior to marketing (pharmaceuticals<sup>13</sup>);
- c) require proof of safety or the control of product use after marketing (existing chemicals under the Toxic Substances Control Act, worker protection, and consumer products<sup>14</sup>);

10. The statutes from which these regulatory systems derive their authority are as follows (listed as ordered in the text): Clean Air Act (CAA), 42 U.S.C. §§ 7401-7642 (1982); Clean Water Act (CWA), 33 U.S.C. §§ 1251-1376 (1982); Resource Conservation and Recovery Act (RCRA), 42 U.S.C. §§ 6901-6987 (1982); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y (1982); Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-392 (1982); Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601-2629 (1982); Occupational Safety and Health Act (OSHA), 29 U.S.C. §§ 651-678 (1982); and Consumer Product Safety Act (CPSA), 15 U.S.C. §§ 2051-2083 (1982).

11. Technology-forcing refers to the tendency of a regulation to force industry to develop new technology. Regulations may force development of new technology by different types of restrictions. For example, air and water pollution regulation focuses on "end-of-pipe" effluents. *See, e.g.*, CAA, §§ 111, 112, 202, 42 U.S.C. §§ 7411, 7412, 7521; CWA, § 301, 33 U.S.C. § 1311. OSHA, in contrast, regulates chemical exposures incident to the production process. *See* OSHA, § 6, 29 U.S.C. § 655. The FDCA, FIFRA, and TSCA impose a pre-market approval process on new chemicals. *See* FDCA, §§ 409, 505, 21 U.S.C. §§ 348, 355; FIFRA, § 3, 7 U.S.C. § 136a; TSCA, § 5, 15 U.S.C. § 2604. The degree of technology-forcing ranges from pure "health-based" mandates, such as those in the ambient air quality standards of the Clean Air Act, to a technology diffusion standard, such as "best available technology" under the Clean Water Act, CAA, § 109(b)(1), 42 U.S.C. § 7409(b)(1); CWA, § 301(b), 33 U.S.C. § 1311(b). For a discussion of this issue and a comparison of statutes, see LaPierre, *Technology-forcing and Federal Environmental Protection Statutes*, 62 IOWA L. REV. 771 (1977).

12. *See* FIFRA, § 3, 7 U.S.C. § 136a; FDCA, §§ 409, 505, 21 U.S.C. §§ 348, 355; TSCA, § 5, 15 U.S.C. § 2604.

13. *See* FDCA, § 505, 21 U.S.C. § 355.

14. *See* TSCA, § 6, 15 U.S.C. § 2605; OSHA, § 6, 29 U.S.C. § 655; CPSA, § 7, 15 U.S.C. § 2056.

- d) control production technology to reduce risks to workplace health and safety;<sup>15</sup> and
- e) control emissions, effluents, or wastes (air, water, and hazardous waste regulation<sup>16</sup>).

Furthermore, the internal structure of regulations may alter the general climate for innovation. Elements of that structure include:

- a) the form of the regulation (product versus process regulation);
- b) the mode (performance versus specification standards);
- c) the time for compliance;
- d) the uncertainty;
- e) the stringency of the requirements; and
- f) the existence of other economic incentives which complement the regulatory signal.

The distinction between regulation of products and regulation of processes suggests yet a further division.<sup>17</sup> New products differ from existing products, and production process components differ from unwanted by-products or pollutants.<sup>18</sup> Regulations relying on detailed specification standards may discourage innovation while prompting rapid diffusion of state-of-the-art technology. Similarly, though a phased-in compliance schedule may prompt only incremental improvements in technology, it allows a timely industry response.

An industry's perception of the need to alter its technological course often precedes promulgation of a regulation. Most environmental regulations arise only after extended scrutiny of a potential problem by government, citizens, workers, and industry. Prior scrutiny, according to a study done by the Massachusetts Institute of Technology,<sup>19</sup> often has greater effects on industry than formal

15. *See* OSHA, §§ 3(8), 6, 29 U.S.C. §§ 652(8), 655.

16. *See generally* CAA, 42 U.S.C. §§ 7401-7642; CWA, 33 U.S.C. §§ 1251-1376; RCRA, 42 U.S.C. §§ 6901-6987.

17. In practice, product and process regulations may be difficult to distinguish. If a process regulation is stringent enough, it effectively becomes a product ban. Product regulation generally gives rise to product substitution and process regulation generally gives rise to process change. *See* FEDERAL REGULATION AND CHEMICAL INNOVATION, *supra* note 9, at 58. *See also generally* Ashford & Heaton, *supra* note 2.

18. Note, however, that component regulations normally specify elements of the production process designed to prevent undesirable by-products. *See infra* note 35.

19. N. Ashford, D. Hattis, G. Heaton, A. Jaffe, S. Owen & W. Priest, *Environmental Safety Regulation and Technological Change in the U.S. Chemical Industry* (Mar. 1979) (report to the National Science Foundation) (CPA No. 79-6) [hereinafter cited as CPA

rulemaking, because anticipation of regulation stimulates innovation. For example, formal regulation of polychlorinated biphenyls ("PCBs") followed years after the government expressed initial concern.<sup>20</sup> Aware of this concern, the original manufacturer and other chemical companies began to search for substitutes prior to regulation.<sup>21</sup> Similarly, most firms in the asbestos products industry substantially complied with the Occupational Safety and Health Administration ("OSHA") asbestos regulation years before it was promulgated.<sup>22</sup> This preregulation period allows industry time to develop compliance technologies, process changes, or product substitutes, while allowing leeway for it to adjust to ensure continued production or future commercial innovation.

The government's initial show of concern is often, however, an unreliable stimulus to technological change. Both technical uncertainties and application of political pressures may cause uncertainty regarding future regulatory requirements. Nevertheless, regulatory uncertainty is frequently beneficial. Although excessive regulatory uncertainty may cause industry inaction, too much certainty will stimulate only minimum compliance technology. Similarly, too frequent change of regulatory requirements may frustrate technological development.

Regulatory stringency is the most important factor influencing technological innovation. A regulation is stringent either (1) because it requires a *significant* reduction in exposure to toxic substances, (2) because compliance using existing technology is costly, or (3) because compliance requires a *significant* technological change. Policy considerations dictate different degrees of stringency as well, since some statutes require that standards be based predominantly on environmental, health, and safety concerns, some on existing technological capability, and others on the technology within reach of a vigorous research and development effort. In the early 1970's, most environmental, health, and safety regulations set standards at a level attainable by existing technology.<sup>23</sup>

Chemical Industry Study]. Results of this study were published in FEDERAL REGULATION AND CHEMICAL INNOVATION, *supra* note 9.

20. See *infra* text accompanying notes 44-58.

21. *Id.*

22. W. Priest & S. Bengali, A Microeconomic Study on Productivity: Impact of OSHA Regulation of the Asbestos Industry, A Collection of Case Studies (Nov. 1981) (CPA No. 81-26) [hereinafter cited as CPA Asbestos Study].

23. LaPierre, *supra* note 11, at 837.

The regulations reflected both a perceived limit to legislative authority and substantial industry influence over the drafting of standards. More recent regulations have tended toward greater stringency.<sup>24</sup>

The effect of the agency's strategy on innovation is not confined to standard-setting. Innovation waivers,<sup>25</sup> which stimulate innovation by allowing noncompliance with existing regulation while encouraging the development of a new technology, are affected by enforcement strategies as well.<sup>26</sup> The degree to which the requirements of a regulation are strictly enforced may influence the willingness of an industrial sector to attempt to innovate. The implementing agency ultimately may strictly enforce environmental regulations against those firms receiving waivers or, alternatively, it may adopt a "fail-soft" strategy where a firm has made an imperfect effort, but good faith attempt to comply.<sup>27</sup> The latter strategy is an important element of the regulatory stimulus to innovation as it decreases an innovator's risk of severe agency action in the event of failure.<sup>28</sup>

### B. Characteristics of the Responding Industrial Sector

The industry responding to regulation may be the regulated industry, the pollution control industry, or a related industry.<sup>29</sup> Regulation of *existing* chemical products or processes might elicit (1) a pollution control device, (2) a manufacturing process change, or (3) a product substitution. The regulated industry will likely supply new processes; the pollution control industry, new devices; and either the regulated industry or new entrants, product substitutions. Regulation of *new* chemicals, however, will simply affect the development of new products.

Recent research on the innovation process has focused on the innovation "dynamic" in diverse industrial segments throughout

24. This article will concentrate on regulations under the CAA, CWA, OSHA, CPSA, RCRA, and TSCA.

25. See *infra* text accompanying notes 140-231.

26. See *infra* text accompanying notes 210-214.

27. *Id.*

28. The authors are indebted to David Foster, Director of the Outreach and Economic Incentives Staff, U.S. Envtl. Protection Agency, for this insight. See *infra* text accompanying notes 210-214.

29. See *supra* Figure 2.

the economy.<sup>30</sup> The model refers to a "productive segment" in industry,<sup>31</sup> defined by the nature of its technology. Over time, the nature and rate of innovation in the segment will change. Initially, the segment creates a market niche by selling a new product, superior in performance to the old technology it replaces. The new technology is typically unrefined, and product change occurs rapidly as technology improves.<sup>32</sup> Because of the rapid product change, the segment neglects process improvements in the early period. Later, however, as the product becomes better defined, more rapid process change occurs. In this middle period, the high rate of process change reflects the segment's need to compete on the basis of price rather than product performance. In the latter stages, both product and process change decline, and the segment becomes static or rigid. At this point in its cycle, the segment may be vulnerable to invasion by new ideas or disruption by external forces that could cause a reversion to an earlier stage.

### C. The Design of Regulatory Strategies

The implications of this model of innovation relate directly to the design of regulation to promote innovation in three ways. First, the model suggests that innovation is predictable in a given industrial context. Second, it asserts that the characteristics of a particular technology determine the probable nature of future innovation within an industrial segment. Third, it describes a general process of industrial maturation which appears relatively uniform across different productive segments. The model does not, however, describe sources of innovation, nor does it elucidate the forces that may transform a mature segment into a more innovative one.

The value of this theory of innovation is that of providing a rationale upon which the designer may fashion a regulation aimed at the industry most likely to achieve his regulatory goal. Consis-

30. In particular, the work of Abernathy and Utterback offers an important model of the differences in the nature of innovation across industries and over time. See Abernathy & Utterback, *Patterns of Industrial Innovation*, *TECH. REV.*, June-July 1978, at 41. For a fuller discussion of the model in the context of regulation, see generally Ashford & Heaton, *supra* note 2.

31. Automobile engine manufacture would be a productive segment as would vinyl chloride monomer production, but neither the automobile industry nor the vinyl chloride industry would be a productive segment since they both encompass too many diverse technologies.

32. It is typical for the old technology to improve as well, although incrementally, when a new approach challenges its dominance.

tently, the theory relies on the assumption that the designer may determine the extent of an industry's innovative rigidity (or flexibility) and its likely response to regulatory stimuli with reference to objective determinable criteria.

Thus the regulatory designer must make the following three determinations:

a) what technological response is desirable (for example, should a regulation force a product or a process change and, further, should it promote diffusion of existing technology, simple adaptation, accelerated development of radical innovation already in progress, or radical innovation);

b) which industrial sector will most likely innovate; and

c) what kind of regulation will most likely elicit the desired response.

The first determination requires a technological assessment, the second a knowledge of a variety of industrial segments, and the third an application of the model considered in this article.<sup>33</sup>

## II. A HISTORY OF STANDARD-SETTING AND THE EFFECTS ON INNOVATION

A brief review of recent regulation and its effect on technological change lends empirical support to the model developed in Section I.<sup>34</sup> The review confirms that product regulations tend to call forth product innovations, that component or pollutant regulations<sup>35</sup> tend to elicit process innovations, and that the stringency of regulation is an important determinant of the degree of technological innovation.<sup>36</sup> In addition, the respondent's techno-

33. A recently completed research report by the Center for Policy Alternatives at the Massachusetts Institute of Technology may be useful to provide a further conceptual basis for designing regulation. See N. Ashford & R. Stone, *Evaluating the Economic Impact of Chemical Regulation: Methodological Issues* (Feb. 1985) (CPA No. 85-01) [hereinafter cited as CPA Economic Methodology Report]. This research reviews and develops methodologies for assessing past and future dynamic regulatory impacts involving technological change.

34. A statistical test of the model using early regulatory history appears in the CPA Chemical Industry Study, *supra* note 19. Much has happened since that study, but no attempt has been made to retest the model statistically.

35. Component regulations specify undesirable elements of the production process while pollutant regulations specify unwanted by-products of the production process. See CPA Economic Methodology Report, *supra* note 33, at 26.

36. More precisely, a relatively high degree of stringency appears to be a necessary condition for inducing more innovative compliance responses. When stringency arises from technology-forcing characteristics of the regulation, the response tends to be more innovative.

logical rigidity helps explain the particular technological solutions adopted.

The following historical review is restricted to regulation after 1970 under the Clean Air and Water Acts,<sup>37</sup> the Toxic Substances Control Act ("TSCA"),<sup>38</sup> the Occupational Safety and Health Act ("OSHA"),<sup>39</sup> and the Consumer Product Safety Act ("CPSA").<sup>40</sup> Furthermore, it is confined to the thrust of the regulation at issue and a summary of the *predominant* technological innovations that followed. This review, therefore, provides neither a complete documentation of the chronology of regulatory events<sup>41</sup> nor a full itemization of industrial responses.<sup>42</sup> Of necessity, the statement of the facts surrounding the regulation must be somewhat subjective and impressionistic. There is a substantial body of evidence, however, both from published studies<sup>43</sup> and anecdotal information to support the analysis.

Table 1 summarizes pertinent characteristics of the ten regulatory cases considered in the review.

Each case contains a description of the regulated substance, the regulated technology, the regulating agency or agencies, the form

TABLE 1

## A Summary of Recent Regulations and the Industrial Responses

Substance	Application	Regulatory Agency	Type of Regulation	Stringency	Industry Response Degree	Industry Response Type
PCBs	All	EPA	Product	Very Stringent*	Radical Incremental	Product Process
CFCs	Aerosol	EPA CPSC	Product	Very Stringent*		Radical Incremental
Mercury	Paint	EPA	Product	Very Stringent	Diffusion	Product
Lead	Paint	CPSC	Product	Very Stringent	Diffusion	Product
Lead	Fuel Additive	EPA	Product	Very Stringent	Incremental	Product
Mercury	Chloralkali	EPA	Process	Stringent	Incremental Diffusion	Process Process
Lead	All Manufacture	OSHA	Process	Very Stringent*		Radical Diffusion
Vinyl Chloride	All Manufacture	OSHA EPA	Process	Very Stringent*	Incremental Diffusion	Process Process
Cotton Dust	All Manufacture	OSHA	Process	Very Stringent		Diffusion
Asbestos	All Manufacture	OSHA	Process	Mildly Stringent	Diffusion	Process

\*Substantial doubt about the standard's technological feasibility at the time the standard was proposed.

37. CAA, 42 U.S.C. §§ 7401-7642 (1982); CWA, 33 U.S.C. §§ 1251-1376 (1982).

38. 15 U.S.C. §§ 2601-2629 (1982).

39. 29 U.S.C. §§ 651-678 (1982).

40. 15 U.S.C. §§ 2051-2083 (1982).

41. Most of the regulations cited were modified several times, and often challenged in court, before the final standard was established. In addition, in certain cases other agencies undertook parallel actions. These details are omitted in order to simplify the discussion. For example, vinyl chloride regulations imposed by EPA and OSHA are considered; however, the bans on the use of vinyl chloride materials imposed by the Consumer Product Safety Commission, the Food and Drug Administration, and the Department of the Treasury (Bureau of Alcohol, Tobacco, and Firearms) are not considered. See CPA Chemical Industry Study, *supra* note 19, at app. A-28 to A-29.

42. In no case was the industrial response to regulation uniform. Even when the predominant response was highly innovative, a few firms selected a noninnovative solution and, in some cases, chose to exit from the industry rather than comply with the regulation. Conversely, some regulatory responses characterized as noninnovative included a few innovative solutions as well, but these were the exception in those industries. For examples of regulation that elicited particularly diverse responses, see *infra* text accompanying notes 76-86 (lead as a fuel additive), *infra* text accompanying notes 87-97 (mercury in the chloralkali industry), *infra* text accompanying notes 98-114 (lead from occupational exposure), and *infra* text accompanying notes 127-135 (cotton dust).

43. See CPA Chemical Industry Study, *supra* note 19; CPA Asbestos Study, *supra* note 22; R. Goble, D. Hattis, M. Ballew & D. Thurston, Implementation of the Occupational Lead Exposure Standard (Oct. 1983) (CPA No. 83-11) [hereinafter cited as CPA Occupational Lead Standard Study]; R. Rutenberg, Compliance with the OSHA Cotton Dust Rule: The Role of Productivity-Improving Technology (Mar. 1983) (submitted under contract to the U.S. Office of Technology Assessment).

of the regulation (product or process), the stringency of the regulation, and the nature of the industrial response, by type and degree of technological innovation. The review begins with product regulations, followed by pollutant and component regulations.

### A. Polychlorinated Biphenyls

Under TSCA,<sup>44</sup> the Environmental Protection Agency ("EPA") prohibited the commercial distribution of PCBs beginning July 1, 1979, and prohibited the manufacture of PCBs beginning January 1, 1980.<sup>45</sup> Regulatory surveillance of PCBs in the United States, however, began as early as 1968,<sup>46</sup> and EPA regulation of PCB effluent discharges began in 1972 under the Federal Water Pollution Control Act Amendments.<sup>47</sup>

In 1970, before EPA took formal action, Monsanto, the sole United States PCB manufacturer, voluntarily restricted PCB sales to closed electrical system uses, such as insulating fluids in transformers and dielectric fluids in power capacitors.<sup>48</sup> In 1976, three years before the EPA manufacturing ban, Monsanto gave one year's notice that it was shutting down its PCB-manufacturing plant.<sup>49</sup> Monsanto's departure from the industry, rather than subsequent EPA regulation, forced PCB users to develop product substitutes.<sup>50</sup>

44. 15 U.S.C. §§ 2601-2629 (1982).

45. TSCA, § 6(e)(2)(A), (e)(3)(A). 15 U.S.C. § 2605(e)(2)(A), (e)(3)(A). Section 6(e)(3)(A) generally prohibits the manufacture of PCBs beginning January 1, 1979, and the processing and commercial distribution of PCBs beginning July 1, 1979. Section 6(e)(2)(A) prohibits the use of PCBs, other than within totally enclosed areas, beginning January 1, 1978. EPA regulations implementing section 6 appear in 40 C.F.R. § 761 (1984).

46. The U.S. Food and Drug Administration began surveillance of PCBs in human and animal food in 1968. See Highland, *PCBs in Food*, ENVIRONMENT, Mar. 1976, at 12.

47. CWA, § 307(a)(2), 33 U.S.C. § 1317(a)(2) (1982). Section 307(a) of the 1972 Act required EPA to develop and publish a list of toxic pollutants and promulgate an effluent standard or ban for any pollutant listed by mid-January 1973. EPA did not publish the first list of nine toxic pollutants, which included PCBs, until nine months after the deadline. See 38 Fed. Reg. 18,044 (1973). EPA promulgated standards for four toxic pollutants, including PCBs, during 1977. See 40 C.F.R. § 129.105 (published in 42 Fed. Reg. 6555 (1977)).

48. CPA Chemical Industry Study, *supra* note 19, at A-14.

49. *Id.* at A-15. Monsanto's actions prior to formal regulation reveal the frequently complex role of public pressure and informal government intervention in stimulating private action. However, it seems appropriate to attribute to the regulatory process Monsanto's initial actions and the subsequent industrial reactions to Monsanto's withdrawal. See also Ashford & Heaton, *supra* note 2, at 120; *supra* text accompanying note 19.

50. CPA Chemical Industry Study, *supra* note 19, at A-15. While PCB capacitor and transformer manufacturers could have imported PCBs from abroad, almost none chose to do so.

There were two types of technological responses to PCB regulation: (1) continued use of PCBs with reduction of associated hazards and (2) development of substitutes.<sup>51</sup> The first response, ultimately abandoned, included Monsanto's introduction of a new, more biodegradable PCB mixture for use in capacitors and a new Westinghouse<sup>52</sup> capacitor design, reducing PCB use by sixty-six percent.<sup>53</sup> The second response was the development of five PCB substitutes. Dow Corning<sup>54</sup> and General Electric<sup>55</sup> independently developed the transformer substitute, a type of silicone (polydimethylsiloxane).<sup>56</sup> The four PCB substitutes for use in capacitors were isopropyl naphthalene, butylated monochlorodiphenyl oxide, di-isononyl phthalate ester, and a mixture of di-octyl phthalate ester with trichlorobenzene.<sup>57</sup> Because these capacitor compounds are more flammable than PCBs, the capacitor manufacturers had to modify the capacitor design slightly, introducing a pressure switch to prevent explosion.<sup>58</sup> Overall, PCB regulation caused modest process innovation and radical and comprehensive product innovation.

The stringency of the regulation derived from its technology-forcing aspects. Consistent with the model, product regulation—in this case, a ban—caused significant product innovation. Technology-flexible (fluid) firms, the new entrants, pioneered the innovation, whereas the rigid Monsanto withdrew.

### B. Chlorofluorocarbons in Aerosol Applications

In 1978, the Consumer Product Safety Commission ("CPSC") and EPA, under TSCA,<sup>59</sup> established rules banning the use of fully halogenated chlorofluorocarbons ("CFCs") from aerosol applica-

51. *Id.* at C-18.

52. Westinghouse is a capacitor firm.

53. CPA Chemical Industry Study, *supra* note 19, at C-18 (citing B. Kerns, Statement Representing Westinghouse Corp., in National Conference on PCBs (Nov. 19-21, 1975) (EPA-560/6-75-004); Telephone interview with Robert Sawyer, Manager of Manufacturing Support, Westinghouse Distribution Apparatus Division (Apr. 26, 1985).

54. Dow Corning is a silicon producer.

55. General Electric is a silicon producer and a transformer manufacturer.

56. CPA Chemical Industry Study, *supra* note 19, at C-19.

57. Telephone interview with Robert Sawyer, *supra* note 53. The first and last were developed by capacitor firms; the second and third were developed by chemical firms in conjunction with capacitor firms.

58. CPA Chemical Industry Study, *supra* note 19, at C-20.

59. 15 U.S.C. §§ 2601-2629 (1982).

tions.<sup>60</sup> These regulations were a direct response to the potential threat CFCs posed to stratospheric ozone.<sup>61</sup>

Two innovative responses resulted from the CFC aerosol ban. First, American Cyanamid<sup>62</sup> developed a non-fluorocarbon propellant, using CO<sub>2</sub>.<sup>63</sup> Second, firms outside the chemical industry developed a new pumping system (called "the pump") not dependent on propellents and cheaper than CFC propellents.<sup>64</sup> The former represented an incremental product innovation, the latter a radical process innovation in can delivery systems.

The stringency of the regulation derived from its technology-forcing aspects. Again, a product regulation stimulated innovation outside the rigid regulated industrial segment.

### C. Mercury in Paint Applications

In 1976, after four years of regulatory proceedings, EPA banned the use of phenyl mercurials in oil-based paint.<sup>65</sup> In oil-based paints, phenyl mercury compounds served both as in-can preservatives and as film preservatives.<sup>66</sup>

The principal industry response to the mercury paint regulation was substitution of existing organic compounds for the mercurials.<sup>67</sup> Although achievement of the desired properties required some paint formulation research,<sup>68</sup> the response was primar-

60. See CPSC Regulations for Self-Pressurized Consumer Products Containing Chlorofluorocarbons, 16 C.F.R. § 1401 (1984); EPA Regulations for Fully Halogenated Chlorofluoroalkanes, 40 C.F.R. § 762 (1984). The Food and Drug Administration also developed regulations banning the use of CFCs in aerosol applications at this time. See FDA Regulations for Use of Chlorofluorocarbon Propellants in Self-Pressurized Containers, 21 C.F.R. § 2.125 (1984).

61. D. Summa, *The Case of Regulating Chlorofluorocarbon Emissions from Non-aerosol Applications 11* (May 8, 1981) (unpublished thesis submitted to the Dep't of Chem. Engineering, Massachusetts Inst. of Technology) (available at the CPA, Massachusetts Inst. of Technology).

62. American Cyanamid is a chemical manufacturer, but *not* a CFC manufacturer.

63. R. Rutenberg, *Regulation Is the Mother of Invention*, WORKING PAPERS, May-June 1981, at 46.

64. *Id.*

65. See EPA Effluent Guidelines and Standards, 40 C.F.R. § 401.15 (1984); EPA Regulations for Paint Formulating Point Source Category, 40 C.F.R. § 446.

66. CPA Chemical Industry Study, *supra* note 19, at C-24.

67. *Id.* at C-23 (citing 209 CHEM. MARKETING REP. No. 13, at 14 (Mar. 29, 1976)). These organic compounds appear to satisfy mildewicide and fungicide requirements, but the durability of the paint has been somewhat impaired.

68. *Id.*

ily adoption of existing technology rather than incremental innovation.

The stringency of the regulation derived from its demand for risk reduction. The immediate availability of suitable substitutes caused diffusion from within the regulated industry rather than innovation.

### D. Lead in Paint Applications

Standards under the Consumer Product Safety Act,<sup>69</sup> the Lead-Based Paint Poison Prevention Act,<sup>70</sup> and the Federal Hazardous Substances Act<sup>71</sup> limited the lead content of household paint to .5% by weight in 1973 and to .06% in 1977.<sup>72</sup> The .5% level effectively prohibited the use of lead pigments, while the .06% level effectively eliminated the use of lead driers.<sup>73</sup>

Industry responded to both effective bans with noninnovative substitution of existing substances. Various organics were already in use as pigments in some paints, and industry expanded their use to replace the lead chromates.<sup>74</sup> For driers, industry had employed combinations of calcium, zinc, zirconium, and lead. Industry simply removed the lead and replaced it with additional quantities of the other chemicals.<sup>75</sup> As with mercury-based paints, diffusion of suitable substitutes from within the regulated industry was the result of the demand for lead reduction.

### E. Lead as a Fuel Additive

Under section 211 of the Clean Air Act,<sup>76</sup> EPA required oil producers and large retailers of gasoline to market at least one

69. 15 U.S.C. §§ 2051-2083 (1982).

70. 42 U.S.C. §§ 4821-4846 (1982).

71. 15 U.S.C. §§ 1261-1276 (1982).

72. See HUD Regulations for Lead-Based Paint Poisoning Prevention in Certain Residential Structures, 24 C.F.R. § 35.12 (1984); CPSC Regulation of Products Subject to Other Acts Under the Consumer Product Safety Act, 16 C.F.R. § 1145.2 (1984); CPSC Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint, 16 C.F.R. § 1303.

73. CPA Chemical Industry Study, *supra* note 19, at C-24.

74. *Id.*

75. *Id.* However, the organic pigments are more expensive than the lead chromates, and the non-lead driers do not work as well, particularly under conditions of low temperature and high humidity.

76. 42 U.S.C. § 7545 (1982).

grade of "lead-free" gasoline after July 1, 1974.<sup>77</sup> This regulation was designed to protect catalytic converter emission control systems.<sup>78</sup> Further, after October 1, 1979, EPA required a reduction in the lead content of regular gasoline.<sup>79</sup>

The oil companies and the chemical industry responded in several ways. First, they substituted the existing manganese-based additive MMT for lead.<sup>80</sup> MMT, however, was found to plug the catalytic converter and was subsequently prohibited by EPA.<sup>81</sup> Second, a "lead trap" was developed which captured the lead in the exhaust and prevented its release to the environment.<sup>82</sup> Although the innovation was a technical success, the adoption of the catalytic converter made it unusable, since the lead trap was not efficient enough to prevent poisoning of the catalyst.<sup>83</sup> Third, the removal of lead, an anti-knock compound, prompted increased catalytic cracking and reforming, at considerable expense.<sup>84</sup> In response, the petroleum refinery industry developed new catalysts, making the cracking process more efficient and less costly.<sup>85</sup> The first response was noninnovative and unsuccessful, the second was quite novel, but commercially unsuccessful, and the third was a successful incremental innovation. Overall, the industry response was a partially successful incremental product innovation.<sup>86</sup>

The stringency of the regulation derived from its technology-forcing aspect. The variety of innovative responses illustrates the technological flexibility of the industry.

77. "Lead free" gasoline may not contain more than 0.05 grams of lead per gallon. See generally CAA, § 211, 42 U.S.C. § 7545 (1982) (implemented by EPA Regulations on Fuels and Fuel Additives, 40 C.F.R. § 80.22(b) (1984)).

78. 40 C.F.R. § 80.1. See also CPA Chemical Industry Study, *supra* note 19, at A-8.

79. Regulations required a reduction in lead content at large refineries to 1.1 grams per gallon. See 40 C.F.R. § 80.20.

80. CPA Chemical Industry Study, *supra* note 19, at A-10.

81. *Id.* (citing *Concern over Effects on Automobile Catalytic Converters Prompting Government/Industry Struggle on Fuel Additive MMT*, [8 Current Developments] ENV'T REP. (BNA) 464 (July 22, 1977); *EPA Bans Octane Booster MMT, Cites Damage to Catalytic Converters*, [9 Current Developments] ENV'T REP. (BNA) 913 (Sept. 15, 1978)).

82. CPA Chemical Industry Study, *supra* note 19, at C-16.

83. *Id.*

84. Ashford & Heaton, *supra* note 2, at 132 n.57.

85. *Id.*

86. The new product, unleaded gasoline, necessitated process innovation. The interrelation of process and product innovation is sometimes very important in the development of new chemicals.

### F. Mercury in the Chloralkali Industry

Under the Federal Water Pollution Control Act Amendments of 1972,<sup>87</sup> EPA established effluent standards for existing mercury chloralkali plants limiting mercury discharges to a maximum of 0.28 grams per 1000 kg. of product for any one day by July 1977.<sup>88</sup> In addition, under the Clean Air Act, EPA promulgated an emission standard applicable to mercury chloralkali plants limiting mercury discharges to 2300 grams over a 24-hour period.<sup>89</sup>

Industry responded in three major ways to the mercury effluent standards.<sup>90</sup> First, it separated the process water and cooling water streams so that the cooling water no longer could come in contact with mercury.<sup>91</sup> Second, it treated the process water stream by a variation of a sulfide precipitation process to remove almost all the mercury.<sup>92</sup> Third, in some cases, it dug up all of the sewer pipes, inspected them for trapped mercury, and cleaned or replaced them.<sup>93</sup> The first response was a significant process innovation by the regulated industry. Although the idea of sulfide precipitation was not new,<sup>94</sup> its application in the second response was an incremental innovation. The third response, of course, was not innovative.

Industry responded to the Clean Air Act requirements by diffusion of existing pollution control devices.<sup>95</sup> Primarily, combinations of mist eliminators, refrigeration, chemical scrubbing, "molecular sieves," and carbon adsorption removed the mercury mist and vapor in the gas stream.<sup>96</sup> In addition, industry introduced

87. Federal Water Pollution Control Act Amendments of 1972, Pub. L. No. 92-500, 86 Stat. 816 (codified as amended at 33 U.S.C. §§ 1251-1376 (1982)).

88. EPA Effluent Guidelines and Standards for Inorganic Chemicals, 40 C.F.R. § 415.62(a) (1984). In addition, the average of daily values for 30 days is limited to 0.14 grams per 1000 kg. of product. *Id.* Furthermore, for new plants, mercury discharges must not exceed 0.23 grams per 1000 kg. of product for any day, and the 30-day average must not exceed 0.10 grams per 1000 kg. of product. 40 C.F.R. § 415.65(a).

89. EPA Regulations on National Emissions Standards for Hazardous Air Pollutants, 40 C.F.R. § 61.52.

90. CPA Chemical Industry Study, *supra* note 19, at C-11 (citing CHEM. ENG'G, Feb. 3, 1975, at 36).

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.* at C-11 to C-13.

96. *Id.* at C-12 (citing CHEM. & ENG'G NEWS, Feb. 14, 1972, at 15).

several housekeeping improvements, including epoxy floors (to prevent mercury buildup in cracks) and tight covers for mercury containers.<sup>97</sup>

### G. Lead from Occupational Exposure

OSHA promulgated the current occupational lead standard in 1978, setting the permissible exposure limit (PEL) at 50  $\mu\text{g}/\text{m}^3$  averaged over eight hours, to be satisfied through a combination of engineering controls, work practices, and administrative controls.<sup>98</sup> Since the standard was explicitly technology-forcing, however, OSHA granted the major affected industries long lead times before it required engineering compliance. The standard granted primary smelting a ten-year exemption, and secondary smelting and battery manufacture five-year exemptions.<sup>99</sup> The OSHA lead standard also required biological monitoring.<sup>100</sup>

The primary smelting, secondary smelting, and battery manufacture industries responded, in part, by a combination of source-reducing controls, worker isolation, and improved work practices.<sup>101</sup> Source-reducing engineering and ventilation control included enclosing and ventilating dust-emitting processes and automating certain processes.<sup>102</sup> Isolation techniques involved surrounding the worker with control booths or cabs with filtered air.<sup>103</sup> Work practices included improved worker training and better

97. *Id.* at C-12. An additional effect of the combined mercury regulations was closure of a few plants and a halt of the construction of new mercury cell plants. Conversely, the regulations have accelerated the development of a membrane cell which allows production of mercury cell-quality caustic without the use of mercury. Unfortunately, the membrane technology suffers from poor durability of the membrane itself, which leads to poor electrical efficiency as the membrane ages. *Id.* at C-12 to C-13.

98. Occupational Safety and Health Standards Subpart Z—Toxic and Hazardous Substances, 29 C.F.R. § 1910.1025(c) (1984). Actually, the OSHA standard does not require the 50  $\mu\text{g}/\text{m}^3$  standard to be met under all conditions. Rather it requires that, when air values are above this value, all "feasible" engineering control measures be taken to reduce them. CPA Occupational Lead Standard Study, *supra* note 43, at 3-55 (citing 29 C.F.R. § 1910.1025(e)).

99. 29 C.F.R. § 1910.1025(e). In the interim, compliance with the standard could be achieved through employee use of respirators. *Id.*

100. 29 C.F.R. § 1910.1025(d). See also CPA Occupational Lead Standard Study, *supra* note 43, at 2-27; Ashford, Spadafor & Caldwell, *Human Monitoring: Scientific, Legal and Ethical Concerns*, 8 HARV. ENVTL. L. REV. 263, 270 (1984).

101. CPA Occupational Lead Standard Study, *supra* note 43, at 3-58.

102. *Id.*

103. *Id.*

housekeeping practices such as frequent cleaning to lessen dust accumulation on floors.<sup>104</sup> Most of these process changes involved the diffusion of existing technology.

Industry produced some innovative responses as well. The primary smelting industry developed a new "direct smelting" process in place of the traditional sinter machine and blast furnace.<sup>105</sup> The direct smelting process converts lead sulfide to lead metal in one step, substantially reducing lead exposure.<sup>106</sup> The secondary smelting industry developed two process innovations. One involved the use of a shaft furnace,<sup>107</sup> improvements in the battery breaking process, and revised dust-handling in the exhaust gases.<sup>108</sup> The other used an improved covered system for conveying molten lead from the smelting furnace and improved ventilating systems for conveying dust from the workplace.<sup>109</sup> In addition, a third secondary smelting process innovation is on the drawing board. Oxygen enrichment will be used in the blast furnaces to reduce lead fumes.<sup>110</sup> Here, technology-forcing regulation dramatically revitalized the innovative potential of a rigid, mature industry. This response is the kind of change Klein's concept of restructuring would predict.<sup>111</sup>

Finally, the battery industry *accelerated* its development of a product innovation and introduced a new process technology. The accelerated product innovation was a shift to smaller batteries, containing less lead and relying on lead-calcium rather than lead-antimony alloys.<sup>112</sup> The new process technology, adapted primarily for use with the new lead-calcium alloy batteries, was the "expanded metal" process for forming battery grids.<sup>113</sup> Instead of casting the grids from molten lead in the conventional process, a coil of metallic lead sheet is cut at intervals, expanded, pressed, and pasted. This process minimizes dust after the paste has

104. *Id.*

105. *Id.* at 3-62.

106. *Id.*

107. Previously, industry had used a traditional two-stage reverberatory/blast furnace system. *Id.* at 3-63.

108. *Id.* However, this secondary smelting technology does not fully meet the 50  $\mu\text{g}/\text{m}^3$  standard by engineering controls alone. *Id.* at 3-64.

109. *Id.*

110. *Id.*

111. See *supra* note 4.

112. CPA Occupational Lead Standard Study, *supra* note 43, at 3-65.

113. *Id.*

dried.<sup>114</sup> In sum, the dominant industry response was the introduction of radical product and process innovations. This was the response of a technology-flexible (fluid) battery industry.

### H. Vinyl Chloride

The regulation of vinyl chloride occurred within a short time amid a crisis atmosphere following its identification as a human carcinogen. The 1974 OSHA final standard limited vinyl chloride exposure to 1 ppm averaged over an eight-hour period with a 5 ppm ceiling averaged over a fifteen minute period.<sup>115</sup> In 1976, EPA, under the Clean Air Act,<sup>116</sup> developed emissions standards for vinyl chloride monomer ("VCM") and polyvinyl chloride ("PVC") plants.<sup>117</sup> The EPA standards limited stack emissions, required control of fugitive emissions, and forced stripping of PVC resins in order to remove residual vinyl chloride monomer ("RVCM").<sup>118</sup> The technological feasibility of both the OSHA and the EPA vinyl chloride standards was questioned at the time the regulations were proposed.<sup>119</sup>

The PVC polymerization industry was most affected by the OSHA and EPA vinyl chloride standards.<sup>120</sup> In response, the industry: (1) installed continuous monitoring devices to identify a vinyl chloride leak; (2) installed dual seal pumps and dual rupture disks on the reactors to reduce leaks; (3) combined condensation, adsorption, and incineration to reduce the VCM concentration in the process vent-gas stream; (4) modified the reactant recipe to reduce resin buildup inside the reactor; (5) automated reactor cleaning systems, obviating the need to open the reactor; and (6) developed improved stripping technology to reduce resin han-

114. *Id.*

115. Occupational Safety and Health Standards Subpart Z-Toxic and Hazardous Substances, 29 C.F.R. § 1910.1017(c) (1984).

116. 42 U.S.C. § 7412 (1982).

117. EPA Regulations on National Emissions Standards for Hazardous Air Pollutants, 40 C.F.R. § 61.65 (1984) (pursuant to CAA, § 112, 42 U.S.C. § 7412).

118. Both the OSHA and EPA standards are essentially pollutant regulations; however, each contains elements of a component regulation as well. For example, the OSHA regulation specified protective equipment and the EPA regulation specified stripping procedure in order to eliminate RVCM. See 29 C.F.R. § 1910.1017(f), (g), (h); 40 C.F.R. § 61.64.

119. See CPA Chemical Industry Study, *supra* note 19, at app. A-26 to A-28.

120. *Id.* at C-2.

dling.<sup>121</sup> The last three responses were all *accelerated* incremental process innovations, and were to be expected from a technology-flexible (fluid) industrial segment. The first three were merely diffusion of existing technology.

The OSHA regulation did not severely affect the VCM manufacturers. They were able to achieve compliance by tightening valves and fixing leaks.<sup>122</sup> The EPA regulation did require, however, the introduction of incineration to reduce the vent-gas streams to the required VCM concentration.<sup>123</sup>

Finally, the PVC plastics fabricators were covered only by the OSHA regulation. The fabricators' problem resulted from RVCM which remained in the resins as they came from the polymerizers.<sup>124</sup> The fabricators reduced VCM concentrations using three approaches: (1) extra ventilation, (2) minimizing worker exposure by automating materials handling tasks, and (3) driving off the RVCM in a controlled way during the first processing step.<sup>125</sup> The last two approaches were incremental process innovations. The PVC polymerizers, however, provided the primary solution to the fabricators' problem. As suppliers responding to the OSHA regulation, they removed most of the RVCM before delivering the PVC resins to the fabricators.<sup>126</sup>

### I. Cotton Dust

The 1984 final OSHA cotton dust standard established permissible exposure limits of 200  $\mu\text{g}/\text{m}^3$  for yarn manufacturing, 750  $\mu\text{g}/\text{m}^3$  for slashing and weaving operation, and 500  $\mu\text{g}/\text{m}^3$  for all other processes in the cotton industry and for other non-textile

121. *Id.* at C-2 to C-9. By sealing the reactor to reduce leakage (in the second and fifth responses), the PVC polymerization firms also improved their production yield since less material was lost during processing. This phenomenon, of unintended benefits related to compliance with a regulation (usually caused by indivisible results of investment decisions or by, as here, conjoint characteristics of the compliance technology) is too pervasive to be considered a curiosity. See CPA Economic Methodology Report, *supra* note 33, at 15.

122. CPA Chemical Industry Study, *supra* note 19, at C-9.

123. 40 C.F.R. §§ 61.62-61.66. See also CPA Chemical Industry Study, *supra* note 19, at C-9.

124. CPA Chemical Industry Study, *supra* note 19, at C-2.

125. *Id.* at C-3.

126. *Id.*

industries where there is exposure to cotton dust.<sup>127</sup> The standard was intended to take effect in September 1978, but court challenges<sup>128</sup> shifted the compliance date until March 1984.<sup>129</sup>

The OSHA cotton dust standard probably prompted, and certainly accelerated, the full-scale modernization of the United States textile industry.<sup>130</sup> That modernization and the associated compliance with the OSHA standard were accomplished not by radical or even incremental innovation, but by the broad diffusion of existing textile technology,<sup>131</sup> most of which was developed in the 1960's.<sup>132</sup> Examples of major process substitution included replacing manual feeding in cotton opening rooms with automatic equipment, using chute-fed cards to eliminate manual carding and manual cleaning, shifting from conventional ring spinning to open-end spinning, and replacing shuttles with shuttleless looms.<sup>133</sup> The relationship between the new technology and the cotton dust emissions was crucially interactive. On the one hand, the new equipment produced much less cotton dust; on the other, the new equipment was more sophisticated and highly sensitive to dust.<sup>134</sup> Modernization in textile technology both required and caused reduced cotton dust emissions. In short, improved productivity and compliance with cotton dust standards were synergistic efforts. Commentators have convincingly argued that the U.S. textile industry has derived a net benefit from the OSHA cotton dust regulation.<sup>135</sup>

### J. Asbestos

The 1972 OSHA asbestos standards limited airborne asbestos particles in the workplace to five fibers per cubic centimeter.<sup>136</sup>

127. Occupational Safety and Health Standards Subpart Z-Toxic and Hazardous Substances, 29 C.F.R. § 1910.1043(c) (1984).

128. See, e.g., *American Textile Mfrs. Inst. v. Donovan*, 402 U.S. 490 (1981); *AFL-CIO v. Marshall*, 617 F.2d 636 (D.C. Cir. 1979).

129. See 29 C.F.R. § 1910.1043(c)(3)(iii).

130. R. Ruttenberg, *supra* note 43, at 61.

131. Ruttenberg calls this adoption "technology-forcing." *Id.* at 43-45. However, in this article the term is used in a narrower sense, reserving it for innovation, and not diffusion, of technology.

132. *Id.* at 62.

133. *Id.*

134. *Id.* at 73.

135. *Id.* at ii.

136. Occupational Safety and Health Standards Subpart Z-Toxic and Hazardous Substances, 29 C.F.R. § 1910.1001(b)(1) (1984).

The asbestos industry, most plants of which were at least thirty years old at the time of the OSHA regulation, responded primarily by adopting pollution control technology.<sup>137</sup> It enclosed manufacturing operations under hoods and covers and introduced vacuum systems to remove fly asbestos fibers.<sup>138</sup> By failing to impose a more stringent standard, arguably necessary to protect workers' health, OSHA lost the opportunity to accelerate new product development and encourage product substitution.<sup>139</sup>

### III. INNOVATION WAIVERS

Some commentators have argued that traditional modes of regulation are a limited approach to reducing environmental pollution and that new incentive approaches will more effectively stimulate the technological innovation necessary to achieve desired levels of air and water quality.<sup>140</sup> A few have contended that market forces such as entrepreneurial risk taking, cost reduction, and profit maximization should be used to encourage private firms to develop innovative technology for pollution control.<sup>141</sup>

In the early 1970's, the National Bureau of Standards commissioned a series of studies to explore possible modifications in regulatory policy, practices, and procedures to encourage firms to innovate.<sup>142</sup> The studies, completed in 1976, examined such mechanisms as effluent taxes, tax subsidies, joint research and development pooling, and innovation waivers. This section examines one of those mechanisms, the innovation waiver, now incorporated

137. CPA Asbestos Study, *supra* note 22, at 19.

138. *Id.* A few firms, such as those in the asbestos-reinforced plastics sector, developed asbestos substitutes, but the consensus of the industry was that substitute products lacked the versatility and performance of asbestos. In addition, some substitutes, such as fiberglass, had their own associated health risks. *Id.* at 17.

139. See generally NIOSH-OSHA ASBESTOS WORK GROUP, *WORKPLACE EXPOSURE TO ASBESTOS: REVIEW AND RECOMMENDATIONS* (1980) (DHHS (NIOSH) 81-103); U.S. ENVTL. PROTECTION AGENCY, *PROCEEDINGS OF THE NATIONAL WORKSHOP ON SUBSTITUTES FOR ASBESTOS* (1980) (EPA 560/3-80-001).

140. Watson, *An Annotated Bibliography of Literature on Market Mechanisms and Economic Incentives for Environmental Regulation*, in DEP'T OF COMMERCE ETIP POLICY RESEARCH SERIES, VOL. 5, *INCENTIVES FOR TECHNOLOGICAL INNOVATION IN AIR POLLUTION REDUCTION* (Oct. 1979) (NBS-GCR-ETIP 80-90).

141. *Id.*

142. The studies are summarized in J. BOOTH & Z. COOK, *AN EXPLORATION OF REGULATORY INCENTIVES FOR INNOVATION: SIX CASE STUDIES* (Aug. 1979) (NBS-GCR-ETIP 79-66). See also J. BOOTH & Z. COOK, *TAXONOMY OF INCENTIVE APPROACHES FOR STIMULATING INNOVATION* (Aug. 1978) (NBS-GCR-ETIP 78-53).

into several federal pollution control statutes.<sup>143</sup> The examination will evaluate the effectiveness of innovation waivers appearing in the Clean Air Act, the Clean Water Act, and RCRA.

Innovation waivers are incentive devices built into environmental regulations. Generally, the waivers extend deadlines by which industry must install pollution control equipment to meet emissions permit limitations. Development of an innovative idea into an operational reality often requires trial periods and substantial time, during which a firm can incur penalties from violations of emissions or effluent standards. The innovation waiver exempts industry from penalties during trial periods and offers it the prospect of cost savings derived from a superior technology.

The waivers provide the opportunity for entrepreneurs, who propose to employ innovative technologies to meet environmental standards, to proceed within a relaxed regulatory atmosphere. In theory, the waivers encourage industry to develop new pollution control and hazardous waste disposal technologies that are either more effective than existing technologies, less expensive, or both. In practice, they have not achieved their intended effect.

The Clean Air Act Amendments of 1970<sup>144</sup> and the Federal Water Pollution Control Act Amendments of 1972<sup>145</sup> were ambitious regulatory schemes, technology-forcing in their focus. The 1970 Clean Air Act required EPA to establish uniform national ambient air quality standards ("NAAQS").<sup>146</sup> In addition, the Act required EPA to establish nationally uniform emission limitations with respect to new stationary sources,<sup>147</sup> hazardous air pollutants from either new or existing stationary sources,<sup>148</sup> and new motor vehicles.<sup>149</sup> New source performance standards ("NSPS") for stationary sources were intended to reflect the best available control technology, taking into account the cost of compliance. The motor vehicle standards applied stringent emission limitations to auto-

143. CAA, §§ 111(j), 113(d)(4), 42 U.S.C. §§ 7411(j), 7413(d)(4) (1982); CWA, § 301(k), 33 U.S.C. § 1311(k) (1982); Hazardous and Solid Waste Amendments of 1984, Pub. L. No. 98-616, § 214, 98 Stat. 3221, 3243 (1984) (to be codified at RCRA, § 3005(g), 42 U.S.C. § 6925(g)).

144. Pub. L. No. 91-604, 84 Stat. 1676 (codified as amended at 42 U.S.C. §§ 7401-7642).

145. Pub. L. No. 92-500, 86 Stat. 816 (codified as amended at 33 U.S.C. §§ 1251-1376).

146. CAA, § 109, 42 U.S.C. § 7409.

147. *Id.* § 111, 42 U.S.C. § 7411.

148. *Id.* § 112, 42 U.S.C. § 7412.

149. *Id.* § 202, 42 U.S.C. § 7521.

mobiles, requiring ninety percent reductions over uncontrolled emission levels by 1975-76, with limited provision for the extension of deadlines.<sup>150</sup>

The ambitious standards established under the 1970 Act proved to be difficult to achieve.<sup>151</sup> The Act established rigid deadlines for compliance and gave the primary responsibility for attaining the NAAQS to the states. By 1976, it was clear that many air quality areas were not going to meet the deadlines for attaining the ambient standards. Tension between the statutory requirements and the need for continued economic growth led to pressure for a revised federal policy.<sup>152</sup>

The national experience under the 1972 Federal Water Pollution Control Act was similar to that under the 1970 Clean Air Act. The 1972 Water Act imposed pollution control methods on industrial dischargers in two phases: (1) industry was required to employ the "best practicable control technology" ("BPT") by July 1, 1977,<sup>153</sup> and (2) industry was required to employ the "best available technology" ("BAT") by July 1, 1983.<sup>154</sup> Nearly fifteen percent of the industrial dischargers nationwide failed to meet the 1977 BPT deadline.<sup>155</sup> The iron and steel industry had the worst record with forty-six percent of the nation's iron and steel plants failing to meet the deadline.<sup>156</sup> Industry representatives lobbied for statutory

150. Clean Air Act Amendments of 1970, Pub. L. No. 91-604, § 202(b)(1)(A), (B), (b)(5)(A), (B), 84 Stat. 1676, 1690-91 (current version at 42 U.S.C. § 7521(b)(1)(A), (B), (b)(5)(A), (B), (b)(6)(A)).

151. For a comprehensive discussion of the problems of the Clean Air Act of 1970 and the legislative response to those problems embodied in the 1977 amendments, see Davis, Kurtz, Leape & Magill, *The Clean Air Act Amendments of 1977: Away from Technology-Forcing?*, 2 HARV. ENVTL. L. REV. 1 (1977).

152. *Id.* at 5-22.

153. Federal Water Pollution Control Act Amendments of 1972, Pub. L. No. 92-500, § 301(b)(1)(A), 86 Stat. 816, 843 (1972) (codified as amended at 33 U.S.C. § 1311(b)(1)(A)). The complete statutory language is "the best practicable control technology currently available." *Id.* The EPA Administrator defines BPT taking into account various factors including the process employed, the age of the equipment and facilities, the relationship of the cost of the treatment to the benefits of effluent reduction, the engineering aspects, and whatever else he deems appropriate. See CWA, § 304(b)(1), 33 U.S.C. § 1314(b)(1).

154. Federal Water Pollution Control Act Amendments of 1972, Pub. L. No. 92-500, § 301(b)(2)(A), 86 Stat. 816, 845 (1972) (codified as amended at 33 U.S.C. § 1311(b)(2)(A)). The complete language is "best available technology economically achievable." *Id.* The EPA Administrator defines BAT, considering essentially the same factors as for BPT. Compare CWA, § 304(b)(2)(B), 33 U.S.C. § 1314(b)(2)(B) with CWA, § 304(b)(1)(B), 33 U.S.C. § 1314(b)(1)(B).

155. See 123 CONG. REC. 26,691 (1977) (testimony of Thomas C. Jorling, EPA Assistant Adm'r for Water and Hazardous Materials, before the Senate Comm. on Env't and Pub. Works as reported by Sen. Muskie).

156. *Id.* at 26,695 (remarks of Sen. Muskie).

extensions of the 1977 BPT deadline, arguing that EPA's tardiness in issuing final guidelines on effluent limitations for some industries did not allow firms sufficient time to comply. In addition, many industrial groups cited serious financial and technological difficulties in developing compliance technology in time to meet the deadline.<sup>157</sup>

The 1970 Clean Air Act and the 1972 Water Act were amended in 1977.<sup>158</sup> The amendments to both statutes represented a move away from the purely regulatory approach of the previous amendments to one manifesting a greater willingness to use market incentives to achieve statutory goals. Each of the statutes was amended to include, among other things, innovation waivers, which constituted an attempt by Congress to foster economic growth while ensuring public health and environmental protection.

### A. The Clean Air Act

#### 1. The Waiver Provisions

The Clean Air Act contains two innovation waiver provisions.<sup>159</sup> One encourages new sources to innovate, the other focuses on existing sources. The new source innovation waiver appears in section 111(j) of the Clean Air Act.<sup>160</sup> It grants the EPA Administrator authority to waive NSPS "to encourage the use of an innovative technological system or systems of continuous emission reduction."<sup>161</sup> Section 111(j) allows a waiver after notice and opportunity for public hearing if:

a) the proposed technology has not been "adequately demonstrated";<sup>162</sup>

157. See *Federal Water Pollution Control Act Amendments of 1977, Hearings Before the Subcomm. on Envtl. Pollution of the Senate Comm. on Env't and Pub. Works, Part 8, 95th Cong., 1st Sess. 516-18; id., Part 10, at 551, 755-56* (testimony of industry representatives). For a comprehensive review of the 1972 Federal Water Pollution Control Act Amendments and revisions made by the CWA of 1977, see Voytko, Hunciker & Lazarus, *The Clean Water Act and Related Developments in the Federal Water Pollution Control Program During 1977*, 2 HARV. ENVTL. L. REV. 103 (1977).

158. Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685 (codified as amended at 42 U.S.C. §§ 7401-7642 (1982)); Clean Water Act of 1977, Pub. L. No. 95-217, 91 Stat. 1566 (codified as amended at 33 U.S.C. §§ 1251-1376 (1982)).

159. CAA, §§ 111(j), 113(d)(4), 42 U.S.C. §§ 7411(j), 7413(d)(4) (1982).

160. 42 U.S.C. § 7411(j).

161. CAA, § 111(j)(1)(A), 42 U.S.C. § 7411(j)(1)(A).

162. *Id.* § 111(j)(1)(A)(i), 42 U.S.C. § 7411(j)(1)(A)(i).

b) the proposed technology "will operate effectively";<sup>163</sup>

c) "there is a substantial likelihood" that the proposed technology will either reduce emissions below that required by NSPS or achieve a reduction equivalent to NSPS "at lower cost in terms of energy, economic, or nonair quality environmental impact";<sup>164</sup>

d) the owner or operator of the proposed technology has demonstrated that it will not "cause or contribute to an unreasonable risk to public health, welfare, or safety";<sup>165</sup> and

e) granting the waiver "will not prevent attainment and maintenance of any national ambient air quality standards."<sup>166</sup>

Under section 111(j), the EPA Administrator determines the duration of the innovation waiver, which may not exceed seven years after the issue date or four years after the source begins operation.<sup>167</sup> If the innovative technology fails, the waiver is terminated.<sup>168</sup> In that case, the statute grants the innovator up to three penalty-exempt years to comply by means of conventional technology.<sup>169</sup>

The existing source waiver appears in section 113(d)(4) of the Clean Air Act. It is a delayed compliance order offered as one of several enforcement options rather than a waiver expressly designed to promote technological innovation. An existing source violating a standard may apply for a section 113(d)(4) order if:

a) it proposes to use a new means of emission limitation which is "likely to be adequately demonstrated . . . upon expiration of the order";<sup>170</sup>

b) it is "not likely" to use the innovative technology unless a section 113(d)(4) order is granted;<sup>171</sup>

c) its proposed technology has "a substantial likelihood" of either reducing emissions below the applicable standard or achieving an equivalent reduction "at lower cost in terms of energy, economic, or nonair quality environmental impact";<sup>172</sup> and

163. *Id.* § 111(j)(1)(A)(ii), 42 U.S.C. § 7411(j)(1)(A)(ii).

164. *Id.*

165. *Id.* § 111(j)(1)(A)(iii), 42 U.S.C. § 7411(j)(1)(A)(iii).

166. *Id.* § 111(j)(1)(B)(i), 42 U.S.C. § 7411(j)(1)(B)(i).

167. *Id.* § 111(j)(1)(E), 42 U.S.C. § 7411(j)(1)(E).

168. *Id.* § 111(j)(1)(D)(ii), 42 U.S.C. § 7411(j)(1)(D)(ii).

169. *Id.* § 111(j)(2)(A), 42 U.S.C. § 7411(j)(2)(A).

170. *Id.* § 113(d)(4)(A), 42 U.S.C. § 7413(d)(4)(A).

171. *Id.* § 113(d)(4)(B), 42 U.S.C. § 7413(d)(4)(B).

172. *Id.* § 113(d)(4)(C), 42 U.S.C. § 7413(d)(4)(C).

d) its compliance with the applicable standard would be "impracticable prior to, or during, the installation" of the innovative technology.<sup>173</sup>

The section 113(d)(4) order can extend to five years from "the date on which the source would otherwise be required to be in full compliance with the requirement."<sup>174</sup> The wording has sparked debate over the effective starting date of the order, but EPA recognizes the required compliance date in the source's State Implementation Plan ("SIP").<sup>175</sup> Although section 111(j) provides a three-year, penalty-exempt compliance period if the innovation fails, section 113(d)(4) provides no extensions beyond the five-year period.<sup>176</sup>

## 2. Implementation of the Waivers

Congress intended the innovation waivers incorporated into the Clean Air Act Amendments of 1977 to encourage industry to develop innovative pollution control technology. The waivers, however, generally have failed to elicit that response. A study of the Clean Air Act waivers conducted in 1980 for the Experimental Technology Incentives Program ("ETIP") of the Department of Commerce involved a survey of activity under sections 111(j) and 113(d)(4), interviews of EPA personnel involved with innovation waivers, and reports on industry's perception of the waiver application process.<sup>177</sup> The study revealed that within the first three-year period, few companies had applied for innovation waivers, EPA had granted only one application, and companies that had applied were reluctant to do so again.<sup>178</sup>

173. *Id.* § 113(d)(4)(D), 42 U.S.C. § 7413(d)(4)(D).

174. *Id.*

175. Evans, *Opportunities for Innovation: Administration of Sections 111(j) and 113(d)(4) of the Clean Air Act and Industry's Development of Innovative Control Technology*, in DEPARTMENT OF COMMERCE ETIP POLICY RESEARCH SERIES, VOL. 3, INCENTIVES FOR TECHNOLOGICAL INNOVATION IN AIR POLLUTION REDUCTION 7 (Jan. 1980).

176. CAA, § 113(d)(4)(D), 42 U.S.C. § 7413(d)(4)(D).

177. Evans, *supra* note 175, at 10.

178. *Id.* at 15, 19-31. The study surveyed the EPA Division of Stationary Source Enforcement (currently known as the Stationary Source Compliance Division) and regional offices and found that, as of January 1980, five applications for section 111(j) waivers had been received; none had been approved, one was denied, one was abandoned, and three were pending. *Id.* at 15. Approximately 18 applications for section 113(d)(4) compliance delay orders had been received; one was approved, six were denied, two were abandoned, six were pending, and the rest were unidentified. *Id.*

The study documented numerous reasons cited by EPA personnel and industry spokesmen for the modest response to innovation waivers. First, agency and industry personnel alike perceived certain legislative directives as ambiguous, resulting in confusion regarding the eligibility of technology for an innovation waiver.<sup>179</sup> Section 111(j)(1)(A) refers to "an innovative technological system" and section 113(d)(4) refers to "new means." The statute does not specify with any particularity what constitutes "new" or "innovative," and thereby grants EPA wide discretion to determine what technology qualifies for a waiver. "Innovative" can refer to a range of activity, including the new application or new combination of existing technologies, the large-scale application of technology previously existing only in laboratory models, or development of a previously unknown, radically different new technology. The agency has not provided guidelines regarding what types of activities within that range it would consider for eligibility.

Agency and industry personnel also perceived subsections 111(j)(1)(A)(i) and (ii) as ambiguous, increasing the uncertainty of a technology's eligibility for a waiver.<sup>180</sup> EPA not only must determine that the proposed technology has not been "adequately demonstrated," but it also must find that it "will operate effectively." Again, the agency has not provided industry with any guidelines relative to the range in which a technology is unproven enough to be "new" and "innovative," but at the same time sufficiently proven to demonstrate that it will operate effectively.

A case documented in the ETIP empirical study reports a prolonged delay in determining whether a proposed technology was innovative.<sup>181</sup> The Homer City site of the Pennsylvania Electric Company ("Penelec") applied for an innovation waiver in November 1977 for a proposed method of reducing its SO<sub>2</sub> emissions. Penelec proposed to meet NSPS and reduce energy, economic, and nonair quality environmental costs by using a new, sophisticated coal cleaning system, known as the Multi-Stream Coal Cleaning System ("MCCS"), rather than conventional scrubber technology. The MCCS is a complex system that physically cleans raw coal in various stages, removing substantial quantities of pyritic sulphur and other impurities. Although coal cleaning itself is not a new technology, the MCCS is unique in the way in which it

179. *Id.* at 8, 37.

180. *Id.* at 7.

181. *Id.* at 23.

blends and refines known technologies and applies them on a large commercial scale. EPA took several years to determine whether the proposed technology was innovative under section 111(j).<sup>182</sup> In this case, both the agency and Penelec would have benefitted from regulatory directives regarding the types of technologies that EPA would consider for eligibility.

The ETIP study concludes that the perceived ambiguity has resulted in confusion and has hampered implementation of the waiver provisions. As noted, EPA possesses considerable discretion to determine what technology is eligible for a waiver. In order to use that discretion wisely to encourage the development of innovative technology, the agency should provide industry with guidelines regarding the parameters of the activity it considers innovative. Detailed interpretative rules are not desirable because they would tend to define the technology that Congress intended industry to invent, and thereby restrict industry's creativity. EPA, however, should provide industry with a balanced interpretation of eligibility which will leave industry neither paralyzed by indecision nor hemmed in by a lack of options.

Industry and EPA personnel also point to statutory time limitations on innovation waivers as disincentives.<sup>183</sup> Section 111(j) limits a new source to seven penalty-free years to develop, install, and refine innovative technology.<sup>184</sup> Should the innovation fail, the statute allows the source up to three years to install conventional technology.<sup>185</sup> Section 113(d)(4) limits an existing source to five years past its SIP compliance date to develop fully and refine its technology. It allows no grace period should the new technology fail.<sup>186</sup> Given the uncertainty inherent in untested processes, the statute's inflexible deadlines may deter some of the innovation that the waivers were designed to promote. Certainly they discourage radical innovation where compliance deadlines must be highly flexible. They would deter incremental and accelerated innovation, however, to a lesser degree.

Constraints in the administration of sections 111(j) and 113(d)(4) have hampered implementation of innovation waivers

182. See Waiver from NSPS for Homer City Unit No. 3 Steam Electric Generating Station, Indiana County, Pennsylvania, 40 C.F.R. § 60.47 (1984).

183. Evans, *supra* note 175, at 17-18.

184. CAA, § 111(j)(1)(E), 42 U.S.C. § 7411(j)(1)(E) (1982).

185. *Id.* § 111(j)(2)(A), 42 U.S.C. § 7411(j)(2)(A).

186. *Id.* § 113(d)(4)(D), 42 U.S.C. § 7413(d)(4)(D).

under the Clean Air Act as well.<sup>187</sup> The EPA Stationary Source Compliance Division ("SSCD"),<sup>188</sup> the enforcement branch of EPA, implements innovation waivers. That task is, perhaps, misplaced. The SSCD was apparently selected to administer section 113(d)(4) because the section appears in the statute under "Federal Enforcement."<sup>189</sup> Since sections 113(d)(4) and 111(j) function similarly, EPA decided that SSCD should administer both.<sup>190</sup> SSCD's mission, however, is enforcement, which may render it unsuited to promote innovation.

The EPA personnel interviewed in the ETIP study claim that SSCD's proclivity for enforcement has distorted its implementation of sections 111(j) and 113(d)(4).<sup>191</sup> SSCD has narrowly interpreted the waiver provisions, fearing a deluge of applications by firms seeking to buy time and avoid noncompliance penalties.<sup>192</sup> Although statutory ambiguity may have justified SSCD's original concern, the flood failed to appear. Nonetheless, the ETIP study indicates that many of the waiver applicants mistook the waivers for automatic exemptions from noncompliance penalties.<sup>193</sup> Firms also have the option of seeking consent decrees to establish new compliance schedules, but consent decrees would not exempt them from noncompliance penalties.<sup>194</sup>

Assigning exclusive authority over the administration of innovation waivers to an office in a position to accord higher priority and greater attention to the program would promote use of the waivers and prevent misuse. The standard-setting office of EPA, or an ombudsman working with the standard-setting office, might administer the waivers more flexibly to encourage industry participation. The standard-setting office possesses the expertise for evaluating existing and potential technological capabilities, for

187. Evans, *supra* note 175, at 10.

188. The SSCD was formerly the Division of Stationary Source Enforcement (DSSE).

189. Evans, *supra* note 175, at 11.

190. *Id.*

191. *Id.* at 10-12. The study indicated that, since SSCD has perceived sections 111(j) and 113(d)(4) as enforcement tools, it has not publicized the availability of innovation waivers and has provided little guidance regarding innovation waivers to regional and local officials. The relatively few applications that it has processed have experienced lengthy delays as a result of becoming entangled in other EPA agenda. The study documents the experiences of several section 111(j) and 113(d)(4) applicants who experienced extensive delays. *Id.* at 19-31.

192. *Id.* at 11-12.

193. *Id.* at 12.

194. See CAA, §§ 113(b), 120(a), 42 U.S.C. §§ 7413(b), 7420(a).

working with industry to establish alternative compliance schedules for innovative technologies, and for assessing the progress of technological development.<sup>195</sup> Whatever office is assigned authority to administer the waiver program, a premium must be placed on certainty in administration, including clarification of the application process. Innovation waiver applications must be processed expeditiously. Otherwise, new applicants will be discouraged from applying, and former applicants will be dissuaded from making future applications.

An additional issue, not raised in the ETIP study but which deserves consideration, concerns the definition of cost in both the Clean Air Act waivers. Both waivers include "nonair quality environmental impact"<sup>196</sup> among the costs that a source may reduce in order to qualify for a waiver. By that inclusion, Congress intended to provide an incentive to develop innovations promoting environmental values as positive benefits. In practice, however, environmental costs are external to industry. Therefore, industry has little incentive to develop new technology to reduce costs it never incurred in the first place. The market solution would be to force industry to internalize all environmental degradation costs, but this is outside EPA's scope of authority under the Clean Air Act. Nonetheless, EPA could ease the Clean Air Act statutory dilemma in part by allowing an innovator's waiver application to rely on compliance savings under other environmental regulations achieved through the technology developed under a Clean Air Act innovation waiver. In addition, the agency could allow an innovator concurrent waivers under different environmental regulations to develop a process reducing different types of environmental degradation.

## B. The Clean Water Act

### 1. The Waiver Provision

Section 301(k) is the sole innovation waiver provision of the Clean Water Act.<sup>197</sup> It authorizes the EPA Administrator to grant

195. Evans, *supra* note 175, at 11, 38.

196. CAA, §§ 111(j)(1)(A)(ii), 113(d)(4)(C)(ii), 42 U.S.C. §§ 7411(j)(1)(A)(ii), 7413(d)(4)(C)(ii).

197. CWA, § 301(k), 33 U.S.C. § 1311(k) (1982). Section 301(k) applies only to existing industrial and municipal point sources that discharge directly into navigable waters

compliance extensions to existing dischargers from the BAT deadline. Dischargers may qualify for extended compliance schedules in two ways: (1) they may install an innovative technology that results in an effluent reduction significantly greater than BAT,<sup>198</sup> or (2) they may install an innovative technology that results in an effluent reduction at the same level as BAT but with the potential to achieve that reduction at a significantly lower cost.<sup>199</sup> In either case, the discharger must show that the proposed technology has the potential for industry-wide application.<sup>200</sup> The technology can take the form of innovative production processes, innovative control techniques, or an innovative system.<sup>201</sup> In no event may the Administrator grant an innovation waiver from BAT effluent limitations past July 1, 1987.

### 2. Implementation of the Waiver

Section 301(k) does not appear to suffer from the same ambiguity regarding eligibility criteria as the innovation waivers under the Clean Air Act. In its final rule for section 301(k), promulgated in June 1984, EPA defines "innovative technology" as "a production process, a pollution control technique, or a combination of the two . . . which has not been commercially demonstrated in the industry of which the requesting discharger is a part."<sup>202</sup> That

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and are thus subject to NPDES permits under section 402. New sources and indirect dischargers (dischargers into publicly owned treatment works) do not come within the ambit of § 301(k). *See* 49 Fed. Reg. 25,979, 25,980 (1984).

198. 49 Fed. Reg. 25,982 (to be codified at 40 C.F.R. § 125.23(a)). "Significantly greater effluent reduction than BAT" has been defined in the final rule promulgated by EPA to mean that the effluent reduction in excess of BAT produced by an innovative technology is significant in comparison to the effluent reduction over best practicable control technology produced by BAT. *See id.* (to be codified at 40 C.F.R. § 125.22(c)).

199. *Id.* (to be codified at 40 C.F.R. § 125.23(b)). "Significantly lower cost" has been defined in the final rule to mean that "an innovative technology must produce a significant cost advantage when compared to the technology used to achieve BAT limitations in terms of annual capital costs and annual operation and maintenance expenses over the useful life of the technology." *Id.* (to be codified at 40 C.F.R. § 125.23(d)).

200. *Id.* (to be codified at 40 C.F.R. § 125.23(a), (b)). EPA interprets industry-wide application to mean that the discharger must demonstrate that the technology can be applied in at least two facilities that are in one or more industrial categories. The use of innovative technology in two or more plants owned by the same corporation is consistent with the definition. *See* 45 Fed. Reg. 25,978 (1984).

201. CWA, § 301(k), 33 U.S.C. § 1311(k). EPA interprets systems to include both production processes and control techniques. 49 Fed. Reg. 25,980.

202. 49 Fed. Reg. 25,981 (1984) (to be codified at 40 C.F.R. § 125.22(a)). The regulations also address the issue of what constitutes "commercially demonstrated" technology and set forth a test for what constitutes a commercial demonstration. The test is whether the technology has been "successfully operated at full scale in a commercial plant for a full

definition should prove helpful to the innovator in judging the novelty of his proposal. Uncertainty may still arise, however, in those cases where a proposed innovation is insufficiently distinct from existing commercial applications to form a separate process or technique.

Another aspect of the Clean Water Act waiver which increases certainty in the application process concerns the requirement that an applicant *demonstrate* that its innovation will result either in significantly lower effluent levels than BAT or in the same effluent levels at a significantly lower cost.<sup>203</sup> A waiver applicant under the Clean Water Act does not confront the same dilemma that an applicant under the Clean Air Act confronts, namely having to show that the innovation will operate effectively while also showing that it has not been adequately demonstrated.<sup>204</sup> In that way, an applicant's uncertainty arises only from the strength of its demonstration, and not from confrontation with a statutory dilemma. Noteworthy is EPA's refusal to define further eligibility for innovation waivers under the Clean Water Act through the publication of a nonexclusive list of eligible technologies. EPA observed that even that measure might "serve to stifle incentive to pursue other options not yet 'approved.'"<sup>205</sup>

Because final guidelines have been promulgated only recently, little empirical data exist to indicate whether these provisions are providing sufficient guidance to EPA and industry in determining eligibility. Some indications, however, suggest an improvement. EPA reports in its publication of the final rule that it "has already received applications for 301(k) extensions which contend that savings of over eight million dollars will result, and that improved effluent treatment will occur."<sup>206</sup>

Like the innovation waivers under the Clean Air Act, section 301(k) appears in the enforcement section of the statute. The administration of section 301(k), however, has not been characterized by the same proclivity for enforcement that characterizes the ad-

cycle of the plant's operations." *Id.* at 25,980. EPA further distinguishes "pilot plant or benchscale operations of the technology from reliance upon the technology in a commercial plant." *Id.*

203. *Id.* at 25,982 (to be codified at 40 C.F.R. § 125.23).

204. Compare 49 Fed. Reg. 25,981, 25,982 (to be codified at 40 C.F.R. §§ 125.22, 125.23) with CAA, § 111(j)(1)(A)(i), (ii), 42 U.S.C. § 7411(j)(1)(A)(i), (ii) (1982).

205. 49 Fed. Reg. 25,979.

206. *Id.* at 25,980, 25,981.

ministration of the innovation waivers under the Clean Air Act. A State Director or EPA Regional Administrator, after consultation with a technical review panel appointed by the Director of the Office of Water Enforcement and Permits at EPA headquarters, decides whether a discharger may receive a waiver.<sup>207</sup> The technical review panel's function is to undertake technical evaluations of proposed technologies, to make uniform determinations on whether technologies are innovative, to determine whether projected performance improvements are significant, and to determine whether they have potential for industry-wide application.<sup>208</sup> In addition, the technical review panel may assess technological viability, thereby reducing the risk of failure in achieving negotiated compliance schedule deadlines.<sup>209</sup>

In the event that a discharger fails to meet an extended compliance deadline under section 301(k), after a good faith effort and where the failure is due to substantial unanticipated problems, EPA has indicated that, in the interests of encouraging the use of 301(k) extensions, it may elect not to impose civil penalties for the violation.<sup>210</sup> Instead, it may enter into consent decrees with expeditious compliance schedules.<sup>211</sup> EPA adopted this "fail-soft" approach in its treatment of Penelec's Homer City plant when Penelec applied for an innovation waiver pursuant to section 111(j) of the Clean Air Act.<sup>212</sup> EPA approved Penelec's application and Penelec subsequently reduced its emissions from a level in excess of 3.0 lbs. SO<sub>2</sub>/million Btu to 1.4 lbs., using an advanced coal cleaning system instead of conventional scrubber technology. Although the reduction by the innovative technology was significant, Penelec failed to attain the required limitation of 1.2 lbs. within the time period established under the compliance schedule.<sup>213</sup> EPA decided not to impose the penalty in consideration of both Penelec's good faith effort to comply and public hearing testimony during the application process indicating that capital investment,

207. *Id.* at 25,979.

208. *Id.*

209. *Id.*

210. *Id.*

211. *Id.*

212. See *supra* text accompanying note 182.

213. Interview with David Foster, Director of the Outreach and Economic Incentives Staff, U.S. Evtl. Protection Agency (Feb. 1, 1985). For the terms of the compliance schedule established under the innovation waiver granted to Penelec for its Homer City plant, see 40 C.F.R. § 60.47 (1984).

operating costs, overall process energy consumption, and waste disposal would all be lower using the new innovative system instead of a conventional scrubber.<sup>214</sup> The development of innovative technology is fraught with complication and delay and constitutes a risky venture under the best of circumstances. Promotion, therefore, requires a "fail-soft" approach. Otherwise, the threat of harsh noncompliance penalties will discourage innovation waiver applications.

Another significant issue under the section 301(k) waiver provision concerns the lack of a broad definition of costs that may be reduced by a source in order to qualify for a waiver. Under the Clean Air Act, a source may be granted a waiver if its proposed technology is likely to meet the standard at a reduced cost. That cost may take the form of "nonair quality environmental impact[s]."<sup>215</sup> The Clean Water Act waiver, however, contains no comparable incentive to develop innovation to promote environmental values as positive benefits. Section 301(k) innovations need only achieve "greater effluent reduction than BAT" or "the same effluent reduction as BAT at a significantly lower cost."<sup>216</sup> The omission represents a danger and a missed opportunity. First, there is a danger that an acceptable innovation might satisfy one or both of the above requirements at the cost of some other significant environmental degradation. The statutory caveat that innovative processes and control techniques must move "toward the national goal of eliminating the discharge of all pollutants" only partially mitigates the danger.<sup>217</sup> Second, unlike the Clean Air Act waiver provision, section 301(k) fails to include innovations which would reduce degradation not covered under the Clean Water Act while maintaining effluent levels required by BAT. Such innovations could reduce unregulated degradation, regulated degradation which does not impose significant costs on the innovator, or any

214. Interview with William H. Foskett, formerly Team Leader, Air Team, Performance Development Inst. (Feb. 1, 1985). See also Evans, *supra* note 175, at 27.

215. CAA, §§ 111(j), 113(d)(4), 42 U.S.C. §§ 7411(j), 7413(d)(4). See also *supra* text accompanying note 196.

216. 49 Fed. Reg. 25,982 (to be codified at 40 C.F.R. § 125.23).

217. CWA, § 301(k), 33 U.S.C. § 1311(k) (1982). Some innovations might involve significant environmental impacts other than pollution. For example, they may use excessive energy or natural resources. This presents a special problem where an innovator proposes to use large quantities of an inexpensive resource such as water. The environmental impact of a large water diversion may well outweigh the pollution savings over BAT proposed by the innovation.

regulated degradation below regulated levels. At best, innovation waivers under the Clean Water Act should account for all costs incurred by the innovator, whether internal or external. In the absence of Congressional action amending the statute, however, EPA should at least interpret the statutory caveat regarding pollutant discharges so as to embrace all kinds of environmental degradation.

Although little empirical data regarding innovation waivers under the Clean Air Act and the Clean Water Act exist, indications are that the provisions have only minimally encouraged technological innovation. The potential for greater utilization, however, does exist. The purpose of the innovation waivers is to stimulate technological innovation beyond the level already required by the existing standards without sacrificing the health, safety, and environmental goals of the statutes. In order to co-optimize those objectives, a regulatory designer must take into account certain considerations when designing regulations to implement the statutes.

An initial consideration concerns the attractiveness of the innovation waiver relative to other compliance options. In fashioning the innovation waiver, the regulatory designer must consider the alternative compliance options available to the regulated industry. If dischargers perceive other options readily available that are cheaper or result in more extensive delays than the innovation waiver, they will have less incentive to develop innovative technologies. On the one hand, compliance options which might diminish the relative attractiveness of innovation waivers include delaying compliance through use of other sections of the statute,<sup>218</sup> obtaining variances, using demonstration grants or industrial development bonds to acquire outside funding or indirect subsidies (both of which would provide an independent incentive to seek innovative techniques), and influencing the writing of regulations and the enforcement of permits.<sup>219</sup> On the other hand,

218. The Clean Water Act does not allow specifically for noninnovation-related compliance delays. In contrast, subsections 113(d)(1) and 113(d)(2) of the Clean Air Act allow specifically for noninnovation-related compliance delays. CAA, § 113(d)(1), (2), 42 U.S.C. § 7413(d)(1), (2) (1982).

219. For a detailed discussion of the alternatives to innovation waivers that are available to firms, see A. Krupnick & D. Yaras, *Innovative Technology Compliance Extensions: A Qualitative Economic Analysis of Section 301(k) of the 1977 Clean Water Act Amendments 3-8 (1981)* (report of the Environmental Policy Evaluation Program, Resources for the Future, Inc.) (available upon request from authors).

tightening funds in other programs, tightening regulations so that noninnovative compliance delays are not readily available, and consistently enforcing permit requirements will enhance the attractiveness of innovation waivers.<sup>220</sup>

In fashioning the innovation waiver, the regulatory designer must define at the outset the goal of the regulation in order to determine the desired responses from industry. Innovation waivers currently are designed to stimulate technological innovation achieving pollution reduction beyond the level already required under regular standards or achieving the required level at less cost. In order to stimulate optimum innovation in pollution control technology, the regulatory designer should not restrict innovation waivers to proposed "end-of-pipe" technology. Instead, he or she should design the waivers to provide a strong incentive to industry to make changes in production processes and product design as well.

Certain mechanisms may help to provide industry with a greater incentive to innovate. As noted above, empirical studies report that industry has voiced concern about time allowances that it perceives as too short for extensive development of innovative technologies. One solution would be a flexible delay period to be determined through negotiation between an innovating firm and an EPA technical review panel. The settlement might include periodic monitoring of the firm's progress and noncompliance penalties to alleviate any cost advantage realized as a result of noncompliance.

An additional incentive to develop innovative technology beyond "end-of-pipe" techniques would be adoption of a "fail-soft" approach if the innovation fails and the firm must resort to conventional technology to comply with limitations. This would diminish the firm's risk of failure. Since developing innovative technology is costly, time-consuming, and risky, firms would perceive strict noncompliance penalties in the event of failure as a strong disincentive. If a firm in good faith attempts to develop and refine new processes to meet the required limits, yet fails, the agency should adopt a sensible enforcement posture that does not unduly

220. Care must be taken not to design and enforce standards so stringently that the regulated industry perceives that massive noncompliance will result. In that case, the perception of massive noncompliance may serve as a disincentive to innovate since widespread noncompliance could result in an amendment of the compliance deadlines. *See id.* at 4.

penalize the firm. To prevent possible abuse, however, the agency should strictly monitor progress in development.

In order to optimize the level of innovation, the regulatory designer must also consider which respondents the waivers should address. The Clean Air Act provides innovation waivers for new sources and for existing sources in violation of their permits. The Clean Water Act provides an innovation waiver only for existing dischargers. In order to optimize innovation, the waivers should be available to both new and existing sources. New sources may be in the best position to innovate. If they perceive the waiver as a strong incentive to innovate, they will be less likely to adopt conventional pollution control technologies and more likely to develop innovative production processes and products. Finally, if the regulatory designer desires diffusion of innovative technology after it is developed, he or she must require that the innovative firm make its technology commercially available as a condition of the waiver.

Finally, the regulatory designer must carefully coordinate management of the program for implementing the innovation waivers in order to instill a high degree of certainty into the program. Firms may not perceive innovation waivers as a strong incentive to innovate unless the agency administers its program with certainty. The program, therefore, should be publicized. In addition, a specially designated group, trained to interact with industry throughout the waiver process, should administer the program. The agency should delineate a set of eligibility criteria so that firms can determine with reasonable certainty whether they may qualify for innovation waivers. Once an application is submitted, it must be processed expeditiously so that the firm will know early in the process—before it incurs extensive costs—whether it definitely will receive a waiver.

### C. Resource Conservation and Recovery Act

Congress recently included an innovation waiver provision in the Resource Conservation and Recovery Act through the Hazardous and Solid Waste Amendments of 1984.<sup>221</sup> The innovation

221. Pub. L. No. 98-616, § 214, 98 Stat. 3221, 3243 (1984) (to be codified at RCRA, § 3005(g), 42 U.S.C. § 6925(g)).

waiver is included in the section of RCRA which sets forth permit requirements for new and existing facilities that treat, store, or dispose of hazardous waste. Because the RCRA innovation waiver was enacted recently, no empirical evidence exists by which to assess its success. A brief examination of its provisions, however, may be useful.

The innovation waiver under RCRA is called a Research, Development, and Demonstration Permit.<sup>222</sup> Under the provision, EPA is authorized to issue permits for activities covered by RCRA but which entail "an innovative and experimental hazardous waste treatment technology or process"<sup>223</sup> for which permit standards have not been established in the regulations. EPA may issue these permits independent of the statute's general permit regulations, except that it may not waive or modify financial responsibility.<sup>224</sup> In addition, EPA may waive or modify its basic permitting procedures in order to expedite permitting, except for procedures under section 7004(b)(2) concerning public participation.<sup>225</sup> The permit may last only one year, with three possible one-year renewals.<sup>226</sup>

The permit does not expressly require a showing of feasibility in advance of allowing an innovative facility to operate. It does provide, however, that permits

shall provide for the receipt and treatment by the facility of only those types and quantities of hazardous waste which the Administrator deems necessary for purposes of determining the efficacy and performance capabilities of the technology or process and the effects of such technology or process on human health and the environment.<sup>227</sup>

Although the permit does not require a showing of feasibility, it must always "include such terms and conditions as will assure protection of human health and the environment."<sup>228</sup> Thus, in theory, the innovator carries the economic risk while risks to the environment are eliminated. In practice, however, risks to human

222. *Id.* (to be codified at 42 U.S.C. § 6925(g)).

223. *Id.* (to be codified at 42 U.S.C. § 6925(g)(1)).

224. *Id.* (to be codified at 42 U.S.C. § 6925(g)(2)).

225. *Id.*

226. *Id.* (to be codified at 42 U.S.C. § 6925(g)(1)(A), (g)(4)).

227. *Id.* (to be codified at 42 U.S.C. § 6925(g)(1)(B)).

228. *Id.* (to be codified at 42 U.S.C. § 6925(g)(1)).

health and the environment do exist because of the uncertain nature of innovative technologies. These risks are partially reduced by the requirement of an annual review and renewal of the permit, and by the authority granted to EPA to terminate all operations at the facility upon a determination that "termination is necessary to protect human health and the environment."<sup>229</sup>

The RCRA waiver provision is, in some ways, fundamentally different from provisions under the Clean Air Act and the Clean Water Act. This difference may be due, in part, to the different targets of their respective statutes. Both the Clean Air Act and the Clean Water Act regulate pollutant discharge levels. RCRA's regulation of hazardous waste treatment facilities, however, sets forth permit standards for particular methods of treating, storing, or disposing of hazardous waste.<sup>230</sup> Thus the RCRA permit enables experimentation with new technologies for which permit standards do not exist.<sup>231</sup> This emphasis on the experimental nature of innovation under a RCRA permit contrasts with the insistence on practical utility of innovation waivers under the Clean Air Act and the Clean Water Act, both of which require varying degrees of demonstration that the innovative technology works before a waiver will be granted.

Although the RCRA innovation permit was recently enacted, several observations can be made regarding its potential success. The RCRA permit is designed to stimulate facilities to make changes in treatment processes, a venture that involves a significant capital investment. An innovator's risk of an adverse regulatory reaction after a significant capital investment is threatening under any of the three statutes. The risk is significant under the Clean Air Act and Clean Water Act because an innovator must enter the waiver application process with a technology sufficiently developed to convince EPA of its probable commercial and environmental practicability. Thus the innovator must expend substantial resources before entering the application process. The RCRA innovation permit, however, reduces that risk. The agency is involved in the project from the start, designing the parameters of the project by issuing the terms and conditions of the permit,

229. *Id.* (to be codified at 42 U.S.C. § 6925(g)(3)).

230. RCRA, § 3004, 42 U.S.C. § 6924 (1982).

231. Hazardous and Solid Waste Amendments of 1984, Pub. L. No. 98-616, § 214, 98 Stat. 3221, 3243 (1984) (to be codified at RCRA, § 3005(g)(1), 42 U.S.C. § 6925(g)(1)).

specifying the types and quantities of waste to be processed, and evaluating the treatment results. Such extensive agency involvement suggests that a project doomed to agency disfavor will be identified at the earliest point possible, thus reducing the innovator's risk of unnecessary investment.

The innovator under the RCRA permit system, however, does face the risk of premature project cancellation, since the agency may cancel a project any time that a partially developed innovation poses a threat, no matter how slight. Innovation will occur optimally in a regulatory climate of reduced economic risk. A premature project cancellation could cause both unnecessary loss of initial investments and loss of a potentially cost-saving innovation.

The three-year limit on the RCRA permit, after which the innovator must comply with general permit requirements, further enhances a facility's risk of failure. The agency's involvement in the design and testing of the project, however, mitigates that risk. Early involvement enables the agency to influence the project with the time limitations in mind. The statute does not specify the consequences of failure.

RCRA accords substantial discretion to EPA in the administration of the innovation permit. EPA can profitably use that discretion in order to further the attractiveness of the permits. Accordingly, it would be well-advised to consider its experiences with innovation waivers under the Clean Air and Clean Water Acts, and administer the program with a high degree of certainty.

### CONCLUSIONS

Based on the history of standard-setting over the last fifteen years and the history of innovation waivers, it should now be possible to approach the design of regulation in a manner that can elicit an appropriate technological response. The key determinations are: (1) what technological response is most desirable, (2) in which industrial segment is it likely to occur,<sup>232</sup> and (3) what form of regulation will bring about the desired result. The latter two will require a comprehensive technological assessment of potential

232. Recall that this requires an examination of the technological dynamics of the industrial sectors (and related sectors) targeted by the regulations and that the key determination is the degree of technological rigidity of those sectors. *See supra* text accompanying notes 30-32.

target industrial sectors. The possible technological responses include a product or process change which can be achieved by (1) diffusion of existing technology, (2) simple adaptation (incremental innovation), (3) accelerated development of radical innovation already in progress, or (4) radical innovation.

Innovation waivers apply mostly to *process* change, are expressly technology-forcing, and do not promote diffusion.<sup>233</sup> The designer will seldom use a waiver mechanism for promoting radical process innovation because of the long time generally necessary to develop the innovation. The designer, however, might well encourage both incremental process innovation and acceleration of radical innovation already underway. Success will require EPA to give early, clear, and certain signals to the developer, minimizing the risk of his technology being found unacceptable. Furthermore, good faith efforts resulting in significant, though not complete, achievement of the pollution reduction goal should be rewarded by "fail-soft" strategies, using appropriate and adjustable economic sanctions.<sup>234</sup>

Standard-setting can be used to encourage all the varieties of technological innovation as well as diffusion for both product and process change. The history over the last fifteen years reveals significant innovation and essential compliance with very stringent regulation.<sup>235</sup> Product-focused regulation primarily elicits a product response (substitution of existing products or a new product). Sometimes the new product (e.g. lead-free gasoline) is accompanied by significant process innovation as well.<sup>236</sup> Process regulation can elicit either a process response or a product change. If a process restriction is stringent enough, product substitution may be the only practical response.

Stringency of regulation can be evaluated in terms of both the extent to which it reduces risks and the extent to which it forces development of new technology. Stringent regulations which do not require new technological solutions may appear sufficient, but

233. *See supra* note 131.

234. *See supra* text accompanying notes 25-28, 210-214.

235. *See supra* text accompanying notes 34-139. Compliance was achieved even though, in many cases, industry argued that compliance with the regulation was doubtful or impossible.

236. *See supra* text accompanying notes 76-86. In the case of lead-free gasoline, the process innovation was a new cracking process. *See supra* text accompanying notes 84-85.

fall far short of their potential to achieve maximum protection. For example, the failure to adopt a 0.1 fiber/cc standard, the lowest level detectable, for worker asbestos exposure inhibited development of substitute products by the asbestos industry.<sup>237</sup> The industry was able to comply with the 2 fiber/cc standard simply by installing existing pollution control equipment.<sup>238</sup> By failing to adopt the more stringent standard, OSHA effectively inhibited new product development and product substitution.<sup>239</sup> Contrary to the widely held belief that too stringent a regulation inhibits innovation, in some cases a standard *not stringent enough* may inhibit innovation.

Stringency may, in practice, be affected by the legislative directive of the agency issuing the regulation. For example, EPA, OSHA, and CPSC have different legislative mandates. Recently, the Office of Management and Budget ("OMB") directed the EPA Office of Toxic Substances to construe the scope of its regulatory authority<sup>240</sup> narrowly and to refer appropriate regulation to other agencies. In particular, OMB directed EPA not to ban three uses of asbestos,<sup>241</sup> but to pass the regulatory responsibility on to OSHA.<sup>242</sup> Since it has questionable authority to ban dangerous substances, OSHA could probably only regulate worker exposure in the manufacturing process or user industries.<sup>243</sup> Thus the direc-

237. See *OSHA-NIOSH Group Urges Elimination of Nonessential Uses, Reduced Limits*, 9 O.S.H. REP. (BNA) 1067 (Apr. 17, 1980). See also *supra* note 139 and accompanying text.

238. See *supra* text accompanying notes 136-139. See also CPA Asbestos Study, *supra* note 22, at 19-21.

239. See *supra* note 139 and accompanying text.

240. TSCA, § 9, 15 U.S.C. § 2608 (1982).

241. *EPA to Shift Responsibility to OSHA, CPSC, Plans to Refer Other Chemical Regulations*, 8 CHEM. REG. REP. (BNA) 1315 (Feb. 1, 1985). Recently, after serious protest by environmentalists and EPA employees, EPA appears to be considering a reversal of the referral policy. *EPA Voids Decision, Scraps Referral Plan; Barnes Says Legal, Policy Issues Unanswered*, 8 CHEM. REG. REP. (BNA) 1443 (Mar. 15, 1985); *EPA Memo Halting the Referral of Asbestos, MDA (March 8, 1985)*, 8 CHEM. REG. REP. (BNA) 1468 (Mar. 15, 1985).

242. OMB also directed EPA to refer regulation where appropriate to CPSC. *EPA to Shift Responsibility to OSHA, CPSC, Plans to Refer Other Chemical Regulations*, *supra* note 241, at 1315.

243. Whether banning a substance for which there exists a suitable substitute is a "feasible" regulatory action under OSHA is an untested subject. See OSHA, § 6(b)(5), 29 U.S.C. § 655(b)(5) (1982). Unlike OSHA, CPSC has clear authority to ban dangerous products. Its authority, however, extends only to consumer products and not to the largely industrial products that were the subject of the proposed EPA referral. See CPSA, §§ 2, 8, 15 U.S.C. §§ 2051, 2057 (1982).

tives would provide for regulation of ambient levels, rather than a ban, encouraging the diffusion of ventilation technology rather than the substitution of new industrial products.<sup>244</sup>

Uncertainty in regulatory signals or agency position can also deter innovation. Faced with uncertainties which create risks that the technology developed will not ultimately be needed or will be unnecessarily costly, potentially innovative industries will simply adopt low-risk existing technology. Thus, only diffusion will occur. Both standard-setting designed to encourage innovation and innovation waivers have encountered problems with regulatory uncertainty in the past.<sup>245</sup>

The preceding discussion focuses on the regulation of *existing* chemicals, though some new chemicals are developed as part of the technological response. If EPA desires to encourage the development of *new* chemicals to replace toxic chemicals currently in use, it must take more definitive actions. First, it must be clear and definite about its pre-manufacturing notification process (PMN) by providing clear guidelines regarding the specific safety evaluations which should be undertaken on different classes of chemicals.<sup>246</sup> Second, it must increase the likelihood of market penetration by appropriate regulation of *existing* toxic chemicals. This consolidation of new and old chemical regulation is essential to effect the desired product transition.

In conclusion, the model of the effects of regulation on innovation applied to the history of standard-setting and innovation waivers over the past fifteen years can contribute to more rational and deliberate design of regulation. The design should combine an assessment of the innovative capacity of the possible responding

244. In Sweden, where asbestos has been banned in many applications, several substitutes have been introduced, many of which (particularly gaskets and friction products) have been developed by U.S. firms. See, e.g., Wis. BUS. J., Sept. 1972, at 47; brochures of Colt Industries and Scan-Pac Manufacturing, Inc. (available upon request from authors).

245. See, for example, *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615 (D.C. Cir. 1973), where the court remanded EPA's decision to deny a one-year suspension of the deadline for strict auto emissions standards. The court observed that if the deadline were strictly enforced, and if any one of the major automobile manufacturers were unable to meet the deadline, "it is a likelihood that standards [would] be set to permit the higher level of emission control achievable by the laggard." *Id.* at 638. In that event, the technological leader (Ford Motor Co.) would suffer detriment having "tooled up to meet a higher standard than [would] ultimately be required." *Id.* The court was "haunted by the irony" of this situation. *Id.* at 637. This kind of uncertainty over whether deadlines will be strictly enforced creates a disincentive to innovate.

246. TSCA, § 5, 15 U.S.C. § 2604 (1982).

industrial sectors with levels and forms of regulation tailored to that capacity. The entire process should reflect a realistic evaluation of the best possible achievable goal. In that way, regulation can be used both to stimulate technological change for health, safety, and environmental purposes and to bring about a desirable restructuring of the industrial process.

## 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 Toxic 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.

### 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.<sup>25</sup> Often, additional needed regulatory measures are not likely to be created or enforced, and informational tools<sup>26</sup> 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-

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<sup>25</sup> 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.

<sup>26</sup> 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.<sup>27</sup>

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<sup>28</sup>, 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.<sup>29</sup> 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:<sup>30</sup>

- 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-

<sup>27</sup> 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).

<sup>28</sup> For a detailed analysis with regard to the problems of generating and distributing risk information see Gawel 1997.

<sup>29</sup> 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.

<sup>30</sup> 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.<sup>31</sup>

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.<sup>32</sup> 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 hazardness of substances to some extent.<sup>33</sup>

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

<sup>31</sup> See also Gusman et al. 1980, p. 79 concerning the uncertainty of the data.

<sup>32</sup> 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.

<sup>33</sup> 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.<sup>34</sup>

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."<sup>35</sup> Thus, essential conditions for applying the precautionary principle are uncertainty and irreversibility.<sup>36</sup> 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 comparison 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."<sup>37</sup> 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.<sup>38</sup> 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

<sup>34</sup> See for example EEA 2001.

<sup>35</sup> Principle 15 of the Declaration of the 1992 UN Conference on Environment and Development (the Rio Declaration).

<sup>36</sup> For an extension of the criteria for the application of the precautionary principle see also Ashford 2005.

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

<sup>38</sup> 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.<sup>39</sup> 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*<sup>40</sup> 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 than 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

<sup>39</sup> 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.

<sup>40</sup> 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<sup>41</sup>. 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

<sup>41</sup> 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<sup>42</sup>. 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<sup>43</sup>. 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<sup>44</sup>.

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 pres-

sure 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<sup>45</sup>. 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.<sup>46</sup>

While in the United States, as well as in the European Union, regulations creating testing obligations for new chemicals<sup>47</sup> 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<sup>48</sup>, 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

<sup>42</sup> See Karkkainen 2001.

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

<sup>44</sup> 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.

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

<sup>46</sup> 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.

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

<sup>48</sup> 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.<sup>49</sup> 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).<sup>50</sup> 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 data publicly 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

<sup>49</sup> For a detailed analysis of this cooperative committee, see Koch 2006.

<sup>50</sup> 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<sup>51</sup>, the European Commission developed proposals for a new regulation, which were published in 2003.<sup>52</sup> The political process started with the publication of the whitepaper in 2001 fo-

cusing on strategies for a future chemicals policy. The new system is called REACH – Registration, Evaluation and Authorization of Chemicals.<sup>53</sup> 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.<sup>54</sup> 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).<sup>55</sup>

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.<sup>56</sup> But so far, the consequences and

<sup>51</sup> 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).

<sup>52</sup> See European Commission (2003) and (2004)

<sup>53</sup> See European Commission (2001)

<sup>54</sup> 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.

<sup>55</sup> 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.

<sup>56</sup> See REACH, Annex I.

sanctions<sup>57</sup> for an exceeding of the PNEC respectively DNEL are not quite clear.<sup>58</sup> 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.<sup>59</sup> 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.<sup>60</sup> 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"<sup>61</sup>. Negative impacts for the economy and innovation should be avoided by

<sup>57</sup> In REACH, Title XIII sanctions are defined very vaguely.

<sup>58</sup> 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).

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

<sup>60</sup> See Ashford and Caldart 1996, 193ff

<sup>61</sup> 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: polychlori-

nated biphenyls, fully halogenated chlorofluoroalkanes, dioxin, asbestos<sup>62</sup> 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.<sup>63</sup> 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

<sup>62</sup> 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 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 pursued. 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.

<sup>63</sup> 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.<sup>64</sup> 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.<sup>65</sup> 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.<sup>66</sup> 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 (Volkh 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 (Volkh 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

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

<sup>65</sup> 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.

<sup>66</sup> 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<sup>67</sup>, although only 250 of the listed chemicals are relevant for Massachusetts.<sup>68</sup> 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

<sup>67</sup> 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.

<sup>68</sup> 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 save 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.

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