“Regulation of Existing Chemicals Under TSCA: Information Disclosure as the Route to Reducing Risk and Increasing Available Data”

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Information Disclosure as the Route to Reducing Risk 
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The Toxic Substances and Control Act (TSCA) empowers the Environmental Protection Agency (EPA) to regulate risk associated with the use of existing chemicals and the introduction of new chemicals into commerce. Due to a number of concerns, however, the authority to regulate existing chemicals under TSCA has enjoyed limited success. A more generic and flexible approach is needed to achieve significant risk reduction for existing chemicals. This paper presents a framework for a generic approach to the regulation of existing chemicals. Under this framework, EPA would officially recognize that the distribution of chemical substances without evaluating and communicating to the user how to avoid operationally undesirable exposures represents an unreasonable risk to health or the environment. Acting under the authority of TSCA, EPA would then generically require suppliers to communicate acceptable exposure levels and information regarding safe use. This framework is consistent with the express policy of TSCA, which states that development of data with respect to the effects of chemical substances and mixtures on health and the environment should be the responsibility of manufacturers and processors of chemicals. The approach outlined here is consistent with and complements initiatives of the Office of Toxic Substances (OTS) and would enable OTS to accomplish some of the fundamental goals of TSCA.

I. INTRODUCTION

The Toxic Substances and Control Act (TSCA), enacted by Congress in 1976, empowers the Environmental Protection Agency (EPA) to regulate the use or introduction of chemicals in commerce based on risk. TSCA grants EPA broad authority to:

1. review and regulate the risk associated with the introduction of new chemicals;
2. require testing of new and existing chemicals;
3. place controls on existing chemicals; and
4. require record keeping and reporting of health and safety information by industry.

In recent years, increased attention has been focused on testing, new chemical regulation, and reporting requirements ("Whatever Happened to the Toxic Substance
Control Act,” GAO Report, October 1988; “EPA’s Chemical Testing Program Has Made Little Progress,” GAO Report, June 1990). EPA has been criticized by Congress and environmental groups for failing to exercise its authority effectively in these areas. EPA has responded to the criticism with new initiatives such as a more workable voluntary testing program, the development of a generic Significant New Use Release (SNUR), and more extensive use of the agency’s data gathering powers for regulation under TSCA as well as other environmental programs.

TSCA was enacted to prevent unreasonable risk of injury to health and the environment by all chemical substances (Toxic Substances Control Act, S. Rep. No. 698, 94th Congress, 2nd Session 3-4). Under the current system of regulating existing chemicals, this fundamental goal of TSCA is not being realized. Because so little attention has been focused on regulating existing chemicals, EPA’s Office of Toxic Substances (OTS) has recently announced new initiatives aimed at breathing life into the existing chemical program (Testimony of Linda J. Fisher, Assistant Administrator for Pesticides and Toxic Substances, U.S. EPA; before House Subcommittee on Environment, Energy and Natural Resources, June 20, 1990, Fisher Testimony at 6-7). These initiatives contain many promising features, including regulation of chemical classes rather than regulation on a chemical-by-chemical basis and collection of toxicity information to ensure that the highest risk chemicals are addressed first through risk assessment and risk management methods (Fisher Testimony at 15-16).

While the announcement of new initiatives in this area is a promising development, the approach proposed by OTS is simply inadequate to address the pressing societal desire for reduction of risk associated with the manufacture and use of existing chemicals. The most significant roadblock to progress is the complex and burdensome rulemaking procedure that implementation of the EPA initiatives noted above will require. The rulemaking procedure requires years of analysis, drafting, and hearings before tangible results are realized. Moreover, the science of chemistry is an ever-changing discipline. Due to the fast pace of scientific and technological advances, rules promulgated under the cumbersome existing program will be obsolete by the time they become effective. Finally, the mammoth undertaking of effectively regulating 60,000, or even the 14,000 high-priority substances identified by OTS, on a chemical-by-chemical or even a class-by-class basis is beyond the resources of any government agency (Fisher Testimony at 7).

It is clear that a more generic and flexible approach is needed to achieve significant risk reduction for existing chemicals. An alternative method that will enable government and industry to work together in this vital concern must be developed. This paper presents a framework for a generic approach to the regulation of existing chemicals. Under this framework, EPA would officially recognize that distribution of chemical substances without evaluating and communicating to the user how to avoid operationally undesirable levels and durations of exposure represents an unreasonable risk to health or the environment (I. Rosenthal and A. J. Ignatowski, “The Operational Material Safety Data Sheet (MSDS)—Decreasing Injury to Employees and the Environment from Substances Not Covered by Specific OSHA Regulations,” Wharton Risk and Decision Processes Center, Working Paper Series, 1990). Acting under the

\footnote{This type of regulation is referred to as “performance-oriented”; i.e., it tells the regulated community what it has to do to comply, but gives them the flexibility to determine how to comply.}
authority of Section 6 of TSCA. EPA would then generically require suppliers to communicate acceptable exposure levels and information regarding safe use. This framework is consistent with the express policy of TSCA, which states that the development of data with respect to the effects of chemical substances and mixtures on health and the environment should be the responsibility of manufacturers and processors of chemicals (TSCA Section 2).

As is developed in greater detail below, this broad-based method of regulation has enjoyed significant success in the United States and represents an increasing international trend. Moreover, the approach outlined here is consistent with and complements initiatives of OTS and would enable OTS to accomplish some of the fundamental goals of TSCA (Fisher Testimony).

II. PRIOR REGULATORY SUCCESS OF THE GENERIC APPROACH

A. Specific Laws and Regulations

A broad and generic approach to regulation has been implemented very successfully by a number of federal and state agencies. The most notable example of implementation of this type of regulation is the Occupational Safety and Health Administration’s (OSHA) Hazardous Communication Standard (HCS). HCS, a single standard, regulates the use of labels, Material Safety Data Sheets (MSDSs), and training to communicate chemical hazard information. To communicate this information properly, chemical suppliers must obtain available accurate and reliable data. As a result, HCS has caused not only increased communication but also a substantial increase in risk assessment through testing and analysis, even though the standard per se does not require such testing and risk assessment.\(^2\)

Similarly, California’s Safe Drinking Water and Toxic Enforcement Act (Prop. 65) mandates warnings prior to exposure for chemicals listed by the state to be carcinogens or reproductive hazards. Once again, Prop. 65 per se does not mandate specific actions other than warnings or the cessation of certain releases; nevertheless, Prop. 65 has caused companies to engage in intensive analyses of products for the presence of listed substances, to lower contaminant levels, to research and generate more accurate exposure information, and to conduct extensive risk evaluations. In addition, a number of companies have modified or reformulated products to remove chemicals listed under Prop. 65 (“California Spurs Reformulated Products,” Wall Street Journal, November 1, 1990, at B-1).

EPA has also enjoyed success with performance-oriented regulation. Title III of the Superfund Amendments and Reauthorization Act (SARA) requires data reporting and the development of emergency response plans in conjunction with state and local authorities. Title III of SARA also requires companies to submit air emission data to EPA. The emission data are used to compile the Toxic Release Inventory (TRI), which is then made directly available to the public. In response to increased public knowledge and scrutiny through the use of TRI, companies have voluntarily acted to monitor

\(^2\) OSHA is building on this success by proposing other generic standards addressing medical surveillance and exposure assessment.
and to reduce emissions. These programs under SARA, like HCS, require increased knowledge and communication of the characteristics of chemical substances.

B. Common Characteristics

Each of the laws or regulations discussed above requires communication of specific information concerning chemical hazards and exposures to be passed from the manufacturer, the supplier, or the generator of the hazardous substance to the person potentially exposed. The information does not pass through an ex ante regulatory approval process, although in each case there are mechanisms for ex post review of the accuracy and sufficiency of the data under the specific law or regulation.

None of the provisions discussed above, however, expressly requires chemical testing or risk reduction, but each law has resulted in a dramatic and effective increase in risk assessment, testing, and risk reduction. There are a number of reasons why this increase occurs under these regulatory programs. The provisions, such as HCS, require hazard descriptions based on findings in specified literature or on agency sources or information available to the manufacturer. Frequently, available information does not provide answers to even the most fundamental questions or mandates warnings that are not well-founded or are excessively alarming. In an effort to address the problems and confusion created by these laws, companies have undertaken to reduce risk and to conduct toxicological testing for a variety of reasons, including:

1. to implement a sound risk management policy;
2. to address customer and/or citizen concerns regarding either the relative importance or the extraneous nature of the information;
3. to establish data sufficient to enable the company not to warn about particular hazards or risks that the company believes are erroneous or deminimus and which may cause undue alarm to customers or local communities; and
4. to address liability concerns.⁴

Thus, these regulatory programs relating to hazard or risk communication cause companies carefully and thoroughly to test chemicals and to evaluate existing data to identify hazards and assess risk. Due to liability concerns, fines, and criminal sanctions arising from failure to test properly and thoroughly, companies simply must strictly comply with these laws. A similar approach could be adopted to regulate existing chemicals under TSCA.

III. INTERNATIONAL TRENDS

There is currently a worldwide trend toward the regulation of chemicals through the use of generic or performance-oriented rules. The most common generic regulations

¹ For example, federal law requires that a material be regarded as a carcinogen if the material contains 0.1% of a carcinogen regardless of the form of the substance. Thus, solid material that is a carcinogen (constituting 0.1% of the whole) which is embedded in another solid material and is unavailable is treated the same as an available gas at 0.1%.

⁴ Any testing or measurements performed for any of the above reasons must be conducted in a fashion that complies with established testing practices to avoid strict liability and negligence actions that can result in fines and criminal sanctions.
in this area require communication of hazard or risk information. Like HCS, these measures have resulted in increased testing and analysis of chemicals and greater knowledge with respect to hazards associated with the safe use of a large number of chemicals.

The European Economic Community (EEC) is currently in the process of adopting a Directive that imposes a general obligation on manufacturers to ensure that their products are safe (Amended Proposal for a Council Directive Concerning General Product Safety, June 11, 1990). More specifically, the EEC Directive requires manufacturers to provide risk assessment information and to take preventative measures to guard against such risks. The Directive also mandates that distributors monitor the safety of marketed products, pass on risk information, and aid in implementation of preventative measures. Like HCS, the EEC measure places the burden squarely on the manufacturer and supplier of the product.

Similarly, in the United Kingdom, the Control of Substances Hazardous to Health (COSHH) regulations, which became effective in October 1989, require employers to conduct a “suitable and sufficient” risk assessment of a hazardous substance before any exposure to employees occurs. The COSHH regulations contain a generic, yet detailed mandatory system for risk assessment and require risk prevention, monitoring, and employee education. The COSHH, through a broad generic rule, places the burden of testing and communication squarely on the supplier of the hazardous substance.

Other regulations require evaluation and communication of hazard information. For example, the International Labor Organization (ILO) has adopted a Convention regarding chemical safety in the workplace (ILO Convention, “Safety in the Use of Chemicals at Work”). The Convention calls for supplier evaluation of chemicals, labeling and hazard information dissemination, and employer-sponsored employee training and protection programs. Again, a generic rule requires specific action by suppliers and employers that use hazardous chemicals. These initiatives demonstrate the growing trend toward “performance-oriented” information-driven regulation of products and particularly of chemicals.

IV. AN ALTERNATIVE APPROACH TO EXISTING CHEMICAL REGULATION

A. Statutory Authority under TSCA

A basic prerequisite for regulation of existing chemicals in a generic manner is that EPA clearly establish its statutory authority under TSCA. To take action on existing chemicals, Section 6 of TSCA requires that EPA determine if the chemicals present an unreasonable risk to health or the environment.\(^6\) (I. Rosenthal, R. L. Keener,

\(^6\) Risk, as opposed to hazard, requires an estimation of the probability of injury from the hazard in question.

\(^6\) The language of TSCA requires that performance-oriented regulation of existing chemicals rest on an agency presumption that the sale of a substance without communicating to the user or employee how to avoid operationally undesirable levels and durations of exposure represents an unreasonable risk. It is well within an agency’s authority to adopt policy presumptions. See Panhandle Producers and Royalty Owners Ass’n v. Economic Regulatory Administration, 822 F.2d 1105, 1110 (D.C. Cir. 1987); Regular Common Carriers Conference v. United States, 628 F.2d 248, 251 (D.C. Cir. 1980).
M. A. Jayjock, and J. E. Plamondon, "Regulating the Introduction of New Chemicals under Section 5 of TSCA: Improving the Efficiency of the Process and Reducing Potential Injury in the Workplace through the Use of Operational MSDS and Exposure Limits." Wharton Risk and Decision Processes Center, Working Paper Series, 1990, (for discussion of "unreasonable risk" and TSCA regulation). The framework set forth here specifically rejects a broad conclusion under Section 6 of TSCA that the use alone of any chemical creates an "unreasonable risk." Instead, this approach calls for the communication of risk and safe use information and failure to communicate such information is the "unreasonable risk."

Specifically, Section 6 of TSCA provides EPA with broad powers to regulate existing chemicals if there is a reasonable basis to conclude that the use of the chemical "will present an unreasonable risk of injury to health and the environment" (15 U.S.C. § 2605). Conversely, it cannot be disputed that at a low enough dose or exposure level, any chemical can be used safely or with "reasonable" risk. Thus, the famous maxim: the poison is in the dose. Accordingly, the introduction into commerce of any chemical without the communication of either explicit or implicit information that will allow the user to avoid injurious doses or exposure levels creates an unreasonable risk.1 Once this prima facie case is established, EPA might appropriately select from a wide range of control actions from requiring hazard warning labels to outright bans on the manufacture or use of especially hazardous chemicals. Under Section 6, EPA could initiate any of the following actions:

(a) prohibit or limit the use of the substance for a particular application in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement;
(b) require warnings and instructions by labels or public notice in a manner prescribed by EPA, including notice of unreasonable risk to persons or the environment; or
(c) require manufacturers and processors to withdraw the product from commerce and conduct the tests to establish concentration/exposure/time limits that define uses of the substance without unreasonable risk to health or the environment.

Because Section 6 empowers EPA to regulate any chemical that presents an unreasonable risk, the statutory provision authorizes the agency to regulate unregulated existing chemicals through the use of a broad, generic rule. Under the system proposed in this paper, it would be established that distribution of any existing chemical absent communication of operational information on how to avoid significant injury would constitute an unreasonable risk. EPA would therefore be empowered to regulate all existing chemicals.5

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1 In contrast, under Section 5 of TSCA, which regulates new chemical substances, the manufacturer of a new chemical provides EPA with the opportunity, through the premanufacture notice (PMN), to require information that the agency needs to inform the user how to use the product without unreasonable risk and to allow EPA to determine if the user is capable of handling the new chemical in the required manner. Under the current interpretation of Section 6, however, EPA must take the initiative to regulate existing chemicals. Section 6 provides no mechanism that ensures automatic and systematic review of existing chemicals as the PMN process does for new substances.

5 Section 5 of TSCA provides an alternative statutory basis for the form of regulation proposed herein. Under Section 5, EPA is authorized to regulate an existing chemical that is being employed in a "significant
B. The Generic Regulation of Existing Chemicals

With statutory authority under Section 6 (or 5) established, EPA could propose a generic rule that establishes that the production and sale of a substance without communicating to the user or employee how to operationally avoid undesirable levels and durations of exposures at which the dose becomes a poison represent an unreasonable risk. More specifically, chemical suppliers would be required to:

(a) establish that under any foreseeable conditions of use that they recommend, or reasonable misuse, exposures will not/cannot take place that lead to significant injury to the user or the environment under foreseeable conditions of misuse; and

(b) provide the user with operational directions that are practical and feasible and that, if followed, protect the user against harmful exposures under conditions of recommended use or reasonably foreseeable misuse.

The supplier of the material would have the burden of proof that either of these two requirements is met and would be required to document compliance. In addition, the supplier would have to provide compliance documentation to the government upon request or to a customer who proves injury and establishes a nexus between injury and use of the chemical substance.

C. Benefits of Generic Regulation of Existing Chemicals

Such a rule under TSCA will require only risk evaluation and the communication of operational information on overexposure and the means of protecting against such overexposure; professional ethics, liability, and insurance concerns will lead to increased generation of toxicological, end use exposure, and personal protective equipment performance data. The decision to use the term “communication” was carefully considered and deliberate in the development of this analysis in that it is entirely reasonable for the supplier to rely on the conservative use of structure–activity relationships (SAR) rather than, for example, testing each compound of a homologous family of materials to obtain data (L. Rosenthal et al., “Regulating the Introduction of New Chemicals Under Section 5 of TSCA: Improving the Efficiency of the Process and Reducing Potential Injury in the Workplace through the Use of Operational MSDS and Exposure Limits,” Wharton Risk and Decision Processes Center, Working Paper Series, 1990). By and large, SAR would be used conservatively by firms since their decisions will need to be documented and the validity of these documented decisions subsequently defended in actions brought by customers, the agency, or other plaintiffs.

Moreover, specific exposure standards would be established de facto for essentially all materials handled in commerce, without the need for specific EPA mandated substance-by-substance or category-by-category regulation. While the risk reduction achieved on any single substance may be less comprehensive than EPA could accom-

new use.” EPA could adopt a policy that any use of a chemical without knowledge and communication of the chemical’s hazardous properties constitutes a significant new use. The EPA could then promulgate a SNUR that would regulate environmental hazard communication in a manner similar to that of OSHA’s HCS.
plish by a substance-by-substance rulemaking, the totality of risk reductions for existing chemicals currently in the marketplace clearly would be far greater than EPA can ever hope to accomplish by relying on its present approach.

With this process in place, EPA could then continue to concentrate its resources on prioritized rulemaking for chemicals based on some combination of:

1. the amounts in commerce;
2. high exposure or emission levels;
3. toxicity indications based on SAR or available toxicity data; and
4. indications that the producers’ findings on exposure levels that avoided unreasonable risk were at variance with SAR indicators.

Specific substance-by-substance rulemaking using a prioritized list could be initiated and progress at the same rate as the present rate. At the same time, the public would enjoy the benefits of “voluntary” determinations of unreasonable risk by the producers. The proposed approach in no way negatively affects the positive thrust of current initiatives, but impacts, supplements, and advances it.