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The Promise and Limits of the United States Toxic Substances Control Act

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Since the 1940s, thousands of new chemical substances have entered the marketplace with little or no pre-market review or control. A substantial portion of these chemicals reached high volumes of production and use, without government intervention and often in the absence of any understanding of their potential adverse health and environmental impacts.

The lack of government oversight of chemicals in commerce changed with the passage of the Toxic Substances Control Act (TSCA) in 1976. Earlier regulation on clean water and air had addressed primarily wastes coming from production processes. These acts generally placed the burden on the Environmental Protection Agency (EPA) to establish standards and demonstrate risks before acting. However, TSCA for the first time exerted government control over production and use decisions, affecting the types of chemicals that could be produced and limitations on their use. The Toxic Substances Control Act allows the EPA to regulate toxic substances in the broadest possible way, from outright banning of chemical substances to testing and labeling requirements.

It is important to note that TSCA's provisions apply differently to new and existing chemicals. A "new chemical substance" is defined as "any chemical substance which is not included in the chemical substance list compiled and published under [TSCA] section 8(b)." This list, called the "TSCA Inventory," is a list of all chemical substances in commerce prior to December, 1979. *All chemicals on the market prior to this date (approximately 99% by volume of what is on the market today) are considered existing chemical substances. These chemicals are considered safe unless EPA can demonstrate that they present an unreasonable risk to human health or the environment.*

While TSCA has had some successes in ensuring review of new chemicals coming to the market since 1980, its impact in terms of gaining information on the toxicity of chemicals and restricting existing chemicals on the market has been limited at best

The provisions of TSCA

TSCA contains a number of provisions designed to address new and existing chemicals. The most important sections of TSCA include the following:

- Section 5: Prohibits the manufacture, processing, or import of a “new chemical substance” or “significant new use” of an existing substance unless a premanufacture notification (PMN) is submitted to EPA at least 90 days before the commencement of manufacture or processing. The PMN contains information on the chemical identity, physical characteristics, processing and use, and available toxicity data. During this 90-day period, EPA reviews the chemical’s human and environmental risks and exposures, examining the data submitted in addition to other information. EPA can then request more data, prohibit or limit manufacture, or halt the review process. The premanufacture submission requirements only apply to chemicals and products of biotechnology for industrial use. Any chemical used as a drug, food additive, or pesticide is covered under different sets of laws. Additionally certain types of chemicals and chemical uses are exempted from the review process and EPA is authorized to make future exemptions.¹
- Section 6: Authorizes the EPA to issue regulations to address the risks of existing substances if “there is a reasonable basis to conclude that . . . a chemical substance or mixture . . . *presents or will present an unreasonable risk of injury to health or the environment* [emphasis added]. . . using the least burdensome requirements” that are necessary to address that risk. Such regulations can be issued immediately when a threat of harm is imminent.
- Section 4: Compels the EPA Administrator to require the testing of chemical substances or mixtures, new or existing, if 1) there are insufficient data to make an unreasonable risk determination and testing is necessary; and 2) the chemical substance or mixture may present an unreasonable risk or the chemical will be produced in substantial quantities and either may enter the environment in substantial quantities or lead to significant or substantial human exposure.
- Section 8: Authorizes EPA to promulgate rules that require chemical manufacturers, processors, and distributors to maintain records and make reports on chemicals and mixtures. This includes requirements to submit health and safety studies, provide immediate notice of “substantial risks,” and maintain records of adverse health effects for 30 years. This section allows EPA to issue rules to collect production and use information as well as information on disposal and byproducts. This includes the Inventory Update Rule, which generates an inventory every four years of all of the non-polymeric chemicals produced or imported into the United States.
- Section 9: Requires the EPA to formally refer regulation of an unreasonable risk to other agencies if that risk “may be prevented or reduced to a sufficient extent under a federal law not administered by the Administrator.” These “referral agencies” include the Occupational Safety and Health Administration and the Consumer Product Safety Commission.

¹ These exemptions include: substances manufactured, processed, or distributed only for export; substances manufactured or processed only in small quantities for research and development, including product development; test marketing, if the substance “will not present any unreasonable risk of injury to health or the environment” as a result of the test marketing activity; non-isolated intermediates (temporary intermediates with no exposure); polymers meeting specific requirements; and Low Volume and Low Release and Exposure, subject to restrictions on use.

The failure of existing chemicals provisions under TSCA

Despite the years of debate over TSCA and great hopes that it would help eliminate a substantial gap in regulation of toxic substances, its implementation has been less than successful, particularly for existing chemicals. In implementing restrictions on the manufacture or use of toxic chemicals the EPA has an extremely high burden to act under TSCA resulting in few chemical restrictions. To restrict such chemicals EPA must prove that the chemical “will present an unreasonable risk”, that it is choosing the least burdensome regulation to reduce risks to a reasonable level, and that the benefits of regulation outweigh the costs to industry. EPA must do this on a chemical-by-chemical basis.

Example: Asbestos and the limits of TSCA.

The EPA’s experience in attempting to regulate asbestos in 1990, demonstrates the near impossibility for EPA to restrict chemicals in commerce through regulatory means. Following ten years of research, public meetings, and regulatory impact analyses in 1989 the EPA issued a final rule under Section 6 of TSCA to prohibit the future manufacture, importation, processing and distribution of asbestos in almost all products. The asbestos industry challenged the EPA’s ban and took its appeal to the Fifth Circuit Court of Appeals. In a landmark case (*Corrosion Proof Fittings v. EPA*), the court all but eliminated the EPA’s ability to use TSCA Section 6 to restrict problem chemicals. Overall, the court held that the EPA had presented insufficient evidence (including risk information) to justify its asbestos ban. The court found that: (1) the agency had not used the least burdensome regulation to achieve its goal of minimizing risk, (2) had not demonstrated a reasonable basis for the regulatory action, and (3) had not adequately balanced the benefits of the restriction against the costs to industry. In its conclusions the court held that “the EPA’s regulation cannot stand if there is any other regulation that would achieve an acceptable level of risk as mandated by TSCA” and that “EPA, in its zeal to ban any and all asbestos products, basically ignored the cost side of the TSCA equation.” Such a sharp reprimand from the court has placed a chill on any further efforts by the EPA to use its Section 6 authority to restrict chemical production or use.

Several government reviews have demonstrated the failure of TSCA to manage existing chemicals. A 1994 report by the U.S. Government Accounting Office (GAO) found that the throughout its existence EPA has restricted only five chemicals (PCBs, chlorofluorocarbons, dioxin, asbestos, and hexavalent chromium).² The GAO also found that the EPA’s referral of chemical risks to other agencies as required under TSCA Section 9 has resulted in only four referrals. Congressional hearings in 1983, 1988, and 1994 highlighted the limitations of the EPA’s existing chemicals program. As early as 1988, Charles Elkins, then Director of the EPA’s Office of Toxic Substances, noted that “it is clear to me that the current level of accomplishment of the existing chemicals program is inadequate.”

Some successes on data collection requirements under TSCA

EPA has had some successes obtaining data on chemical toxicity, use, and exposure under TSCA’s section 4 testing and information provisions. However, even these results have been limited. Although TSCA section 4 provides EPA with authority to require chemical testing, few test rules have been enacted. In part, this is because EPA must first have some data to

² PCBs were banned under TSCA in 1976 and the asbestos ban was overturned by the Fifth Circuit Court of Appeals.

demonstrate that the substance “may present an unreasonable risk or substantial exposure” before requiring more data and must defend its requests for data usually on a chemical-by-chemical basis.

Studies in the 1980s and 1990s by the National Academy of Sciences, the Environmental Defense Fund and the Environmental Protection Agency demonstrated that most industrial chemicals have not undergone even basic toxicological testing. Taking advantage of these reports the EPA entered into a voluntary “challenge” with the American Chemistry Council for industry to provide basic screening level data on the high production volume (HPV) chemicals (the 2800 chemicals manufactured or imported in quantities over 1 million pounds per year) chemicals. The program to date has been moderately successful, with industry consortia “adopting” about 65 percent of the chemicals and producing robust summaries of toxicity data. Although the EPA has put the data summaries on the Internet, the agency has yet to determine how to use incoming data for risk management decisions. EPA officials have noted the HPV challenge to be its most successful effort to date for existing chemicals, however, the program does not cover the more than 6,000 chemicals currently used annually in quantities between 10,000 and 1,000,000 pounds

Other TSCA information provisions have also had some successes. The TSCA Inventory Update Rule has provided important data on chemical production in the United States. Under this program critical use data on existing chemicals have been collected by the EPA. However, for the most part, these provisions have been hampered by two problems: industry’s reluctance to provide risk information and the excessive use of confidential business information claims.

TSCA Section 8 requires that any chemical manufacturer, processor, or distributor who becomes aware of new information which indicates that their chemicals present a substantial risk of injury to human health or the environment must report the information to the EPA. This responsibility was designed to serve as an early warning system. In 1990 the EPA determined that submissions under this requirement were meager and sent a letter to the industries announcing a special amnesty program and urging the industries to submit data they had failed to report. While this amnesty was in effect from 1991-1994 more than 120 companies sent the EPA 11,000 studies or reports of adverse health effects from chemicals on the market that may have never been reported in the scientific literature.

EPA’s ability to provide public information on chemical production and risk has also been hindered by strict confidential business information provisions of TSCA. During early history of TSCA, industry had to substantiate confidentiality claims, claiming confidential information now requires little more than a routine check-off procedure. A 1998 EPA analysis found that 65 percent of the information in industry filings to the agency under TSCA was claimed as confidential. About 40 percent of substantial risk notifications claim chemical identity as confidential.

New chemicals review under TSCA: a bright light

Despite TSCA’s limitations for existing chemicals, the new chemicals program has proven to be a successful example of a precautionary review policy. The new chemicals provisions of TSCA apply at the premanufacture stage (before any marketing has occurred) and place a low initial threshold for agency action: “may present an unreasonable risk to human health or the environment or substantial exposure throughout their production, use, and disposal.” In conducting the premanufacture reviews, the EPA uses a multidisciplinary lifecycle review approach involving long-standing agency scientists to rapidly assess the risks associated with new chemicals. Through *deterrence* from potentially harmful chemicals and *guidance* toward safer

chemicals and production methods, the EPA provides strong signals to manufacturers as to types of chemicals that might present an unreasonable risk and types of chemicals and synthesis pathways that will reduce risks. These mechanisms include:

- *Categories of chemicals.* The EPA has used its “Chemical Categories” list to indicate the types of chemicals and risks that are of concern to the agency and the types of data the agency needs to evaluate those risks. As a result, companies are more likely to present data to avoid the possibility of regulatory orders or to avoid certain chemicals of concern (i.e, the EPA has issued guidance providing strong signals to avoid bringing persistent, bioaccumulative, and toxic substances to market).
- *Informal communication and negotiation with submitters.* The EPA regularly discusses concerns with premanufacture notification submitters. If EPA staff express concern, submitters are not likely to question those concerns because they generally do not have the data to refute them. They either withdraw the chemical or come up with the data. Further, EPA informally advises submitters to modify production process or substances to minimize risks, placing the burden on industry to make such changes.
- *Pollution prevention initiatives.* EPA has set up voluntary programs to encourage the development of safer chemical products and production systems, including providing software to firms to understand chemical risks and safer syntheses. These help to internalize considerations of safety at the earliest points of the research and design phase of chemicals.

While the new chemicals program could be strengthened through the addition of testing requirements as production of new chemicals increases (to avoid repeating the current lack of information problem), the program has proven itself to be efficient and successful. However, the new chemicals program applies to less than 1 percent by volume of the chemicals on the market today.

Conclusions: Voluntary by necessity

TSCA was enacted in 1976 to provide a regulatory framework for the EPA to address chemicals throughout their production, use, and disposal – in essence playing an oversight role in production and product choices. However, the EPA has been unable to use its regulatory powers to control the vast majority of chemicals on the market today, because the bar was set too high to act. While scientific concerns about chemicals at the time TSCA was passed were mainly associated with cancer, acute effects of chemicals, and other clear impacts, increasingly scientists are concerned about more subtle effects that are more difficult to prove conclusively, but appear to have serious public health implications.

Although the EPA has successfully reviewed new chemicals that have come on the market since 1980, there is a stark disconnect between new chemicals and existing chemicals regulation in the United States. The TSCA program for existing chemicals has been considered by many analysts and EPA officials to be a failure. For existing chemicals the full burden rests on the EPA to prove that a substance will present an unreasonable risk and that the benefits of regulation outweigh the costs. Uncertainty favors keeping chemicals on the market. Indeed, the EPA’s lack of power to regulate existing chemicals could actually provide a disincentive to bringing safer chemicals to market. Dr. Lynn Goldman, former EPA Deputy Administrator for the Office of Prevention, Pesticides and Toxic Substances, has effectively summarized the failures of TSCA:

“It is fair to state that the results [of TSCA] have come nowhere close to...the original Congressional intent... Although Congress has shown little interest in doing so, there are many examples of sections that need to be reformed and strengthened. Probably the weakest area concerns the management of risks from chemicals. Because of the Act’s inadequate coverage, when EPA is confronted with new risks...it is unable or unwilling to take action to reduce risks, unless industry is willing to step forward voluntarily on its own. TSCA currently places too high of a bar for the EPA to jump to assure the health of the public and protection of the environment. Under TSCA, existing chemicals are assumed safe until proven guilty, even when found in breast milk and even as toxicology evidence accumulates.”

While the EPA has argued that TSCA requires the agency to engage in voluntary initiatives, the rationale for such initiatives is less one of mandate than one of necessity. It is impossible for the EPA to regulate chemicals in commerce, so the agency is forced to rely on voluntary initiatives such as the HPV challenge program and others³ to gather necessary data and encourage industry to undertake risk management measures. While the EPA has promoted important voluntary efforts such as Design for Environment and Green Chemistry, they are insufficient to ensure that basic data are available on chemicals in commerce and that EPA has an ability to act to restrict problem chemicals or broad classes of chemicals. Although the existing provisions of TSCA could be used more effectively by the EPA, the agency will not be able to substantially address chemical risks to public health or the environment without major revisions to this central chemicals management policy statute.

References:

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³ Such as the Voluntary Children’s Testing Program (designed to gather risk data on 23 chemicals of concern for impacts on children).