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Lynn L. Bergeson, Lisa M. Campbell & Lisa Rothenberg*

Congress enacted the Toxic Substances Control Act (TSCA) in 1976.[1] Despite the passage of over two decades, its core provisions have not been substantively amended.[2] Some believe change is needed, even essential. Indeed, the question of whether TSCA is fundamentally flawed or whether EPA's implementation of it is lacking, has been the subject of debate for years.

While much has changed over the past two decades, this article concludes that TSCA is an essential environmental law that serves a vital role in our society. Further, this article concludes that toxics reporting laws and the transparency that results from compelled disclosure have lessened the need for mandatory chemical testing under TSCA and strengthen, not diminish, TSCA's influence as a potent pollution prevention tool.

TSCA: Past and Present

Legislative History

Preliminary work toward TSCA's enactment began in 1971 after the Council of Environmental Quality (CEQ) issued a report finding that existing regulations to control the potential toxicity of chemical substances were "inadequate" and that there was a "high-priority need for a program of testing and control of toxic chemicals."[3] Congress heeded the message and, in a spectacularly productive legislative session, passed TSCA and the Resource Conservation and Recovery Act (RCRA) within a few weeks of each other.

Congress's impetus for enacting TSCA in 1976 was to respond to several well-publicized public concerns regarding chemical substances in the environment.[4] Congress made its intent for TSCA known in Section 2, which sets forth TSCA's policies:

- Adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment, and the development of such data should be the responsibility of those who manufacture and those who process such chemical substances or mixtures;
- Adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and
- Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic

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> barriers to technological innovation while fulfilling the primary purpose of the Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.[5]

The Senate report on TSCA states that the bill is "designed to fill a number of regulatory gaps which currently exist."[6] For example, Congress was concerned there was a "gap" regarding the premarket review of chemical substances and mixtures.[7] Other "gaps" that Congress intended TSCA to fill include: direct regulation of industrial chemicals for their health and environmental effects; authority to "look comprehensively at the hazards associated" with chemical substances and mixtures; and responsibility for gathering information with respect to health and environmental effects, which, according to TSCA's authors, should be collected from the manufacturers and processors of the chemical substances.

TSCA's Key Provisions

TSCA regulates "chemical substances."[8] TSCA defines the term "chemical substance" as "any organic or inorganic substance of a particular molecular identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical."[9] EPA states: "TSCA defines 'chemical substance' broadly and in terms which cover microorganisms as well as traditional chemicals."[10]

Congress provided EPA with broad regulatory tools to regulate the manufacture, production, and disposal of chemical substances. Key Sections include:

TSCA Section 4—provides authority to promulgate rules requiring manufacturers, importers, and processors to test certain new or existing chemical substances or mixtures for their effects on human health and the environment.

TSCA Section 5—provides authority to regulate new chemical substances prior to their manufacture, import, processing, or distribution for commercial purposes, and to regulate existing chemical substances for significant new uses.

TSCA Sections 6 and 7—provide authority to regulate the manufacture, processing, distribution, use, or disposal of an existing chemical substance or mixture that EPA determines poses an unreasonable risk to human health or the environment, and, for chemical substances or mixtures that EPA determines will present an unreasonable risk of serious and widespread injury to health and the environment before a final TSCA Section 6 rule can be published, the authority to seize that imminently hazardous chemical substance or mixture.

TSCA Section 8—provides authority to promulgate rules to require manufacturers and processors to collect, maintain, and submit data on certain chemical substances; maintain records of allegations of significant adverse reactions; submit health and safety data on certain chemical substances and mixtures; and report any information that a chemical substance or mixture presents a substantial risk of injury to health and the environment.

TSCA Section 9 —sets forth TSCA's relationship to other laws by stating that if EPA determines that an unreasonable chemical risk may be prevented or sufficiently reduced by action under a federal law not administered by EPA, it must refer information on the chemical's risk to the agency administering the other law.

TSCA Sections 12(b) and 13—provide authority to require notification by persons intending to export certain chemical substances as well as promulgate rules regarding the importation of chemical substances.

TSCA Sections 11, 15, 16, and 17—provide authority to inspect facilities for TSCA compliance, issue civil and criminal penalties for TSCA violations, and seize any chemical substance or mixture manufactured, imported, processed, or distributed in commerce in violation of TSCA.

TSCA Section 14(a)—prohibits EPA, except in certain limited circumstances, from disclosing to the public trade secrets, and commercial or financial information that is privileged or confidential.

TSCA Accomplishments

There has been significant debate over the years regarding whether TSCA has fulfilled Congressional expectations. This debate should not eclipse the many accomplishments EPA has achieved over the past two decades. EPA has used its TSCA authority to require the testing of chemical substance and mixtures, gather information on these substances, impose restrictions on new chemical substances of regulatory concern, and impose significant penalties for TSCA violations. Each of these accomplishments is reviewed below.

TSCA Section 4—Test Rules

TSCA Section 4 was enacted in response to the concern that the effects of chemical substances and mixtures on human health and the environment were insufficiently characterized or understood. One of TSCA's stated policies is to ensure that adequate data are "developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances or mixtures." TSCA Section 4 gives EPA broad authority to require the development of adequate test data on the ecological effects, environmental fate, and health effects of such substances. Under TSCA Section 4, EPA can require manufacturers, including importers, and, in some cases, processors, to conduct testing of chemical substances for which EPA makes certain findings.

To require testing, EPA must first find that "there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health and the environment can reasonably be determined or predicted," and "testing of such substance or mixture with respect to such effects is necessary to develop such data." Additionally, EPA must find that the chemical substance is produced in substantial quantities that could result in substantial or significant human exposure or environmental release or presents "an unreasonable risk" to human health or the environment.

Since 1977, the TSCA Interagency Testing Committee (ITC) has been selecting existing chemicals for testing. The ITC was created by Congress under TSCA Section 4(e) as an independent advisory committee to the EPA Administrator. The ITC includes representatives from 15 U.S. Government organizations. TSCA Section 4(e) mandates that ITC establish the TSCA Section 4(e) *Priority Testing List* (chemicals or chemical groups recommended to the EPA Administrator for testing), revise the *Priority Testing List* at least every six months, and submit the revisions as ITC Reports to the EPA Administrator. TSCA Section 4(e) describes criteria that ITC should consider when recommending chemicals or chemical groups.

EPA's Office of Pollution Prevention and Toxics (OPPT) and ITC have reviewed approximately 50,000 of the 70,000 chemical substances listed in the TSCA Chemical Substances Inventory to determine testing needs.[11] ITC has only recommended about ten percent of these existing chemicals for testing, however. In response to ITC's recommendations, EPA has proposed test rules, issued *Federal Register* notices of its decision not to issue a test rule, entered into negotiated testing agreements, enforceable consent agreements (ECA), or voluntary testing agreements with manufacturers, importers, and/or processors to conduct testing in lieu of a test rule, or issued final test rules. As of 1994, there have been approximately: (1) 430 chemicals for which EPA has proposed test rules; (2) 255 chemicals for which EPA has issued a decision not to test; (3) 24 chemicals for which EPA has entered into negotiated testing agreements;(4) 30 chemicals for which EPA has entered into consent agreements; (5) 30 chemicals for which EPA has agreed to voluntary testing agreements; and (6) 120 chemicals for which EPA has issued a final test rule.[12]

ITC and EPA have, therefore, made significant progress in developing testing programs and requiring the submission of data to assist EPA in assessing the toxicity of chemicals of concern. These testing programs have resulted in millions of dollars of testing and risk assessment by industry.[13] As the current ITC Executive Director states: "The ITC's actions have substantially increased the public availability of health effects, chemical fate, and ecological effects data; about 25,000 studies on chemical and chemical groups designated or recommended by the ITC have been submitted under TSCA."[14] It is clear that at least some experts believe that ITC has met Congressional intent that ITC "facilitate coordination of chemical testing sponsored or required by U.S. Government organizations and enhance information exchange to promote cost-effective use of U.S. Government chemical testing resources."[15]

TSCA Section 5—Premanufacture Notices and SNURs

Section 5 is one of TSCA's pivotal provisions. TSCA Section 8(b) directs EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States."[16] This list is known as the TSCA Chemical Substance Inventory (TSCA Inventory). EPA compiled the initial TSCA Inventory in 1977. TSCA defines chemical substances that are listed on the TSCA Inventory as "existing" chemical substances. Chemical substances that are not listed on the TSCA Inventory are considered "new" chemical substances. As of 1999, there are 76,500 chemical substances listed on the TSCA Inventory. TSCA Section 5 provides for the review of new chemical substances, or "significant new uses" of existing chemical substances, before those substances or uses can be introduced in commerce. A determination that a use is both "significant" and "new" must be made administratively by rule, known as a significant new use rule (SNUR).

Under TSCA Section 5, manufacturers and importers must submit premanufacture notices (PMN) at least 90 days before the commencement of manufacture or import of a new chemical substance or new use of an existing chemical substance. The PMN Form seeks information on the submitter's identity, the chemical substance's identity, production volume, uses, exposures, and environmental fate.[17] TSCA does not require a submitter to test new chemical substances before submitting a PMN. Health and safety data relating to a new chemical substance's health or environmental effects that are in a submitter's possession or control, however, must be submitted with the PMN.[18] The submitter must provide this information to "the extent it is known to or reasonably ascertainable by the submitter."[19] During the 90-day PMN review period, EPA evaluates the information to estimate the risk attributable to a new chemical substance and to determine whether an unreasonable risk of injury to health or the environment may occur if the chemical substance is distributed in commerce. EPA is authorized to restrict or ban the manufacture, processing, or distribution in commerce of new chemical substances, and/or designated significant new uses of existing chemical substances.

The new chemicals program is viewed by many in the government and private sector as a premier pollution prevention program. From 1979 to 1994, EPA OPPT's new chemical program reviewed approximately 24,000 new chemical substances. More specifically, EPA reviewed 19,000 PMNs and 5,000 notices seeking an exemption from PMN requirements, including low volume exemptions, low release and low exposure exemptions, test market exemptions, and polymer exemptions.[20] EPA reports that only half of the chemical substances for which PMNs are submitted make it to the marketplace, and only a fraction of those chemical substances in the marketplace are produced at levels above 10,000 pounds a year.[21]

In addition, EPA has signed approximately 1,200 SNURs and issued or negotiated approximately 750 TSCA Section 5(e) consent orders. TSCA Section 5(e) grants to EPA the authority to issue administrative orders controlling new chemical substances where it finds: (1) there is insufficient information reasonably to evaluate the risk; and (2) either the chemical may present an unreasonable risk to health or the environment, or it will be produced in substantial quantities that will enter the environment or

to which there will be substantial or significant human exposure. In its order, EPA can ban or limit the manufacture, distribution, use, or disposal of the chemical or require specific tests or provide for particular disposal controls and worker protection.[22] In approximately 250 cases where EPA has determined that the potential unreasonable risk from exposure to a chemical substance cannot be mitigated by a TSCA Section 5(e) consent order, the manufacturer or importer has suspended further EPA review and undertaken additional testing to address EPA's concerns.[23]

TSCA Section 6—Existing Chemical Regulation

TSCA Section 6(a), perhaps one of TSCA's most controversial provisions, gives EPA broad authority to regulate chemical substances by limiting or eliminating production, importation, or use of a chemical substance if EPA determines that any of those activities causes, or will present, unreasonable risk of injury to health or the environment.

EPA's discretion is not unbridled, however. TSCA Section 6(c) requires EPA to consider four factors in making a determination under TSCA Section 6(a). These are: (1) the effects of a substance or mixture on human health and the magnitude of the human exposure to it; (2) the effects of a substance or mixture on the environment and the magnitude of the environmental exposure; (3) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses; and (4) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health. Under TSCA Section 6, EPA has the burden of justifying that the product it bans presents an unreasonable risk, no matter how many rules exist to control these products.

Using its Section 6 authority, EPA has prohibited the manufacture, processing, and distribution in commerce of fully halogenated CFCs for aerosol propellant uses, except for certain limited uses.[24] EPA also has used its Section 6 authority to issue rules to reduce the potential hazards arising from the use of metalworking fluids.[25] The rules prohibit the mixing of nitrosating agents with certain metalworking fluids. EPA has promulgated regulations under Section 6(a) to address exposure to airborne asbestos in school buildings.[26] EPA additionally has used its Section 6 authority to regulate the use of hexavalent chromium chemicals in certain heating, ventilation, air conditioning, and refrigeration systems based on its findings that such chemicals are human carcinogens.[27]

EPA has not yet successfully used its Section 6 authority to ban a substance. EPA's failure to do so has sparked a heated debate over the legal burden EPA bears in banning chemicals under TSCA Section 6. EPA issued a final rule under Section 6 in 1989 to ban the manufacture, import, and processing of nearly all asbestos-containing products manufactured in the United States.[28] Most of the rule ultimately was set aside, however, by the United States Court of Appeals for the Fifth Circuit.[29] The court found that EPA had failed to consider thoroughly less burdensome regulatory alternatives to a total ban, as TSCA requires. The court also concluded that EPA must consider substitute products, and support the claimed benefits of the proposed rule by evaluating the toxicity of products that would likely be used to replace those made with asbestos.[30] Finally, the court concluded that the rulemaking suffered from procedural defects, including EPA's failure to provide the public with an opportunity for comment on certain exposure methods adopted late during the rulemaking process. The court let stand only those portions of the rule that banned manufacture or importation of asbestos for new uses.

More recently, EPA has sought to exercise its TSCA Section 6 authority in a narrower context. On October 2, 1991, EPA proposed to ban acrylamide and N-methylacrylamide (NMA) grouts.[31] The proposed rule would prohibit the manufacture, importation, distribution in commerce, and use of acrylamide grout as well as all uses of NMA grout except its application for sewer line repair. After a period of three years, the proposed rule would prohibit the use of NMA grout for sewer line repair, and the manufacture, importation, and distribution in commerce of NMA grouts for any purpose. Despite

the passage of almost ten years, and the fact that the rule was at least fifteen years in the making prior to its proposal in 1991, EPA has yet to take final rulemaking action.[32]

TSCA Section 8—Reporting and Recordkeeping Requirements

TSCA Section 8 imposes reporting and recordkeeping requirements on manufacturers, importers, processors, and distributors of existing chemical substances and mixtures. These requirements are summarized below.

TSCA Section 8(a)—authorizes EPA to issue rules, including the Preliminary Assessment Information Reporting (PAIR) Rule, and the Inventory Update Rule (IUR), to require manufacturers and importers of certain chemical substances and mixtures to maintain records and submit reports concerning those chemical substances' and mixtures' production volumes, distribution, use, and human exposure.

TSCA Section 8(b)—authorizes EPA to create an inventory of existing chemical substances.

TSCA Section 8(c)—requires that manufacturers, importers, processors, and distributors of chemical substances and mixtures maintain records of allegations that a chemical substance or mixture may cause significant adverse health or environmental reactions.

TSCA Section 8(d)—requires manufacturers, importers, and processors to submit a copy of any unpublished health and safety study on specified chemical substances or mixtures that are in their possession, lists of unpublished health and safety studies on those chemical substances and mixtures known to them, but not in their possession, and lists of all health and safety studies being conducted by or initiated for the manufacturer, importer, or processor of those chemical substances or mixtures.

TSCA Section 8(e)—requires manufacturers, importers, processors, and distributors to report "substantial risk information" on chemical substances or mixtures to EPA.

TSCA Section 8 is often referred to as TSCA's most successful provision. Most of EPA's TSCA enforcement actions occur for failure to comply with TSCA Section 8's IUR, 8(c) adverse reporting, or 8(d) submission of health effects studies.[33] EPA obtains under its IUR program reports from manufacturers and importers of approximately 9,000 mostly organic chemical substances and mixtures concerning those chemical substances' and mixtures' production volumes, distribution, use, and human exposure. As of April 1998, EPA has received approximately 11,000 submissions under the authority of TSCA Section 8(d).[34] Moreover, manufacturers, importers, processors, and distributors have submitted over 10,000 TSCA Section 8(e) reports on "substantial risk information."[35] EPA recently has developed a database to make TSCA Section 8(e) reports available publicly.

TSCA Section 9

Under TSCA Section 9(a), if the EPA Administrator has a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture will present an unreasonable risk of injury to health or the environment, and determines further that such risk "may be prevented or reduced to a sufficient extent by action taken under a Federal Law not administered" by EPA, EPA must submit to the appropriate agency a report describing those risks. EPA may not take any action with respect to that risk if the agency receiving the report either issues an order declaring that there is not risk of injury to health or the environment or initiates action to protect against such risk. TSCA Section 9(b) provides further:

> The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment is associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such

authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by action taken under this chapter.

EPA has referred to the Occupational Safety and Health Administration (OSHA) for review chemical exposures believed to pose risks pursuant to TSCA Section 9. For example, EPA followed the Section 9 "hand-off" procedure for 4,4'-methylenedianiline (4,4'-MDA) because "[a]ll known human exposure to 4,4'-MDA occurs in the workplace."[36] EPA thus "determined that this risk may be prevented or reduced to a sufficient extent by action taken by ... OSHA .... EPA is submitting to OSHA a report under sec. 9(a) of ... TSCA ... that describes the risks of 4,4'-MDA and requests that OSHA respond to EPA within 180 days of the publication of this notice in the Federal Register."[37]

EPA is pursuing a different pathway in its now ancient 1991 proposed rule banning acrylamide and NMA grouts. The exposures EPA has deemed to pose "an unreasonable risk" in the acrylamide context are purely occupational. TSCA Section 9 thus requires EPA to invite OSHA to address these concerns. Despite this, and criticism from commentors, EPA declined to "hand off" the rulemaking to OSHA to allow it, rather than EPA, to address risk believed to be posed to workers. If the acrylamide and NMA grout ban is ever issued in final, any judicial challenge to it would provide an opportunity for the courts to define judicially, and more precisely, the scope of TSCA Section 9 and EPA's obligation under it to allow other federal agencies to address risks believed to be unreasonable.

TSCA Sections 11, 15-17—Inspection and Enforcement

EPA has a well-established history of bringing administrative enforcement actions and seeking large proposed penalties against chemical manufacturers, importers, and processors of chemical substances and mixtures subject to regulation under TSCA. TSCA Section 15 identifies a broad range of "unlawful activities." These include failure or refusal to comply with a Section 4 test rule or order, or any rule, order, or requirement issued under Sections 5 or 6; use of a chemical substance or mixture for commercial purposes which a person knew or had reason to know was manufactured, processed, or distributed in violation of Sections 5 or 6, or a rule or order already issued under Sections 5, 6, or 7; failure or refusal to establish or maintain records, submit reports, notices, or other information, or permit access to or copying of records required under TSCA Section 8; or failure or refusal to permit entry or inspection as required under Section 11. Like most environmental laws, TSCA is a strict liability statute, and there is no requirement that a violator's conduct be knowing or willful before civil penalties can be imposed under TSCA Section 15.

EPA's Enforcement and Compliance Assurance, FY98 Accomplishment Report states EPA's impressive accomplishments under TSCA's enforcement authority for fiscal year 1998. These statistics show that EPA has conducted 2,926 regional inspections; issued 9 Administrative Compliance Orders; issued 573 Administrative Penalty Order Complaints; reached 622 Administrative Penalty Settlements; referred 10 civil cases to the Department of Justice (DOJ); and issued 11 Civil Judicial Settlements.[38] EPA's report also indicates fines and penalties EPA has collected from its TSCA enforcement efforts. These amounts include: (1) $30,000 assessed in criminal penalties; (2) $25,500 assessed in civil judicial penalties; (3) $3,748,494 in administrative penalties assessed; (4) $3,462,117 in value of injunction relief; and (5) $3,720,065 in value of supplemental environmental projects (SEP).[39]

TSCA Section 14—Confidential Business Information (CBI)

TSCA Section 14(a) prohibits EPA, except in certain limited circumstances, from disclosing to the public trade secrets, and commercial or financial information that is privileged or confidential.[40] TSCA Section 14(a) provides that EPA shall disclose CBI to federal officers or employees in connection with their official duties under laws for the protection of health or the environment, or for specific law enforcement purposes; and to contractors with the

United States, if deemed necessary for the satisfactory performance of their duties in connection with TSCA.[41] Section 14(a) also mandates disclosure of otherwise CBI when EPA determines that disclosure is necessary to protect against an "unreasonable risk of injury to health or the environment."[42] Finally, Section 14(a) permits disclosure of such information when relevant in proceedings under TSCA, but provides that disclosure is to be made "in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding."[43]

TSCA Section 14(b) provides that the prohibitions on disclosure set forth in Section 14(a) do not prohibit the disclosure of a health and safety study and its underlying data, and that a Freedom of Information Act (FOIA) request for such information shall not be denied on the basis of FOIA Exemption 4 (trade secrets). Section 14(b) also specifies, however, that EPA shall not release data that disclose either processes used in manufacturing or processing a chemical substance, or the portion of a mixture comprised by any chemical substances in a mixture.

Congress underscored the protections afforded confidential information provided to EPA under TSCA by providing criminal penalties for wrongful disclosure. TSCA Section 15(d) provides that any officer or employee of the United States who knowingly and wilfully discloses material protected under TSCA shall be guilty of a misdemeanor and fined not more than $5,000 or imprisoned for not more than one year, or both.[44]

EPA's Office of General Counsel (OGC) will issue a determination on a confidentiality claim that is challenged. If EPA upholds the claim of confidentiality, it will notify the claimant that EPA will honor the confidentiality of the materials. If EPA rejects the claim of confidentiality, EPA will advise the claimant that its claim has been denied and that the determination is a final agency action subject to judicial review.[45] EPA will disclose the information unless the claimant acts, within 30 days, to commence an action in federal district court seeking injunctive relief to prevent EPA from disclosing the information.

Concerns With TSCA

Although TSCA's core provisions have not been revised since its enactment, there has been significant debate regarding ways to improve TSCA. In 1994, the General Accounting Office (GAO) issued a report, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*.[46] In response to Congressional concerns that EPA has been slow to implement TSCA, GAO reviewed the legislation and EPA's efforts to: assess chemical substances under TSCA; control those chemical substances found to be harmful; and make TSCA's chemical risk information available publicly. GAO's report reviews the various sections of TSCA, examines problems with its provisions and implementation, and recommends several changes to be made legislatively to improve TSCA. Potential legislative and administrative changes to TSCA were also discussed during hearings held in 1994 before the Subcommittee on Toxic Substances, Research and Development of the Senate Committee on Environment and Public Works.

Discussions have focused primarily on TSCA Section 4's testing authority, Section 5's premanufacture review, Section 6's authority to ban chemical substances and uses, Section 8's reporting and recordkeeping requirements, Section 9's policy on TSCA's relationship to other federal laws, and Section 14's CBI protection. Below is a discussion of various stakeholders' views regarding TSCA sections that have generated the most debate.

TSCA Section 4

Despite EPA's successes in promulgating TSCA Section 4 test rules or similar data requirements, there has been considerable discussion about the paucity of test rules that have been issued over the past two decades. The lack of test rules is considered, in part, to be the result of considerable debate and litigation over what constitutes an "unreasonable risk." Courts have upheld EPA's test rules where, for example, EPA's basis for suspecting the existence of an unreasonable risk of injury to health is "substantial," that is, when there is a more than a theoretical basis for suspecting that some amount of exposure occurs,

and that the substance is sufficiently toxic at that exposure level to present an unreasonable risk of injury to health. *Chemical Mfrs. Ass'n v. EPA*, 859 F.2d 977 (D.C. Cir. 1988), is the seminal case in this regard. It is most often cited for the proposition that a test rule cannot be "based on little more than scientific curiosity," and that EPA can act only "when the existing possibility of harm raises reasonable and legitimate cause for concern."

Issuing Section 4 test rules has proven to be exceedingly time consuming, resource intensive, and thus costly. EPA and industry stakeholders have incurred substantial transaction costs litigating Section 4 test rules. The strain on resources in no small part results from the procedural safeguards EPA has continued to follow. For example, in 1996 EPA proposed a rule requiring the testing of 21 hazardous air pollutants (HAPs) for certain health effects.[47] EPA subsequently extended the comment period five times due to the complexity of the issues raised by various proposals and the need for more time to issue in final various test guidelines. EPA received hundreds of comments on virtually all aspects of the proposed rule, which, by its very name, raised technically complex and legally challenging issues. To date, however, no final rule has been issued.[48]

During the 1994 hearings, then Assistant Administrator for Toxics Dr. Lynn Goldman stated EPA's view that even at the "accelerated" level of testing EPA had initiated in recent years, a testing "gap" still exists compared to the "pace originally envisioned by TSCA."[49] Dr. Goldman stated further that TSCA places a significant burden on EPA by the findings EPA must make and the processes it must use to obtain the test data needed to complete its Section 4 review.[50] In its article *Toxic Ignorance*, EDF (now Environmental Defense) also makes the observation: "In theory [Section 4] authorizes EPA to issue test rules requiring testing and reporting of information, on almost any chemical. Unfortunately, the actual provisions of Section 4 put EPA into a Catch-22: the agency must already *have* data in order to show that it *needs* data."[51]

TSCA Section 5

Under TSCA Section 5, manufacturers and importers are required to submit data on new chemical substances only in specific, narrow circumstances. As a result, approximately half of the new chemical substances reported to EPA are submitted to EPA with no accompanying toxicity data.[52] EPA has attempted to compensate for this lack of data by using structure activity relationships (SAR) to predict and assess health effects or environmental fate of new chemical substances. It has been argued, however, that EPA's PMN review process does not ensure that the potential risks of chemical substances and mixtures are fully assessed before they are distributed in commerce.

Requiring the development and submission of data with a PMN application can present other issues, however. During the 1994 TSCA Hearings, testimony was provided by Hugh M. Smith, then president of the Synthetic Organic Chemical Manufacturers Association (SOCMA). Mr. Smith stated SOCMA's opposition to any amendment to TSCA imposing a mandatory set of data for new and existing chemicals. "A requirement for base set testing (which typically costs from $175,000 - $200,000) for new chemicals would prove to be such an economic hardship for small companies producing low volume specialty chemicals that it would virtually eliminate these companies from the specialty chemical business."[53] The concern of requiring test data is important when considering TSCA's stated policy that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation."

TSCA Section 6

Over the years, EPA has had significant difficulty satisfying the criteria set out in TSCA Section 6. EPA must show that adequate substitutes exist for a chemical it has proposed to ban, and that banning the chemical is the least burdensome choice to minimize risks. As discussed above, the Fifth Circuit Court of Appeals in *In Corrosion Proof Fittings*, invalidated and remanded to EPA its TSCA Section 6 asbestos ban. One of the key reasons for the ruling was the court's determination that EPA failed to assess

adequately alternatives to the ban. Some argue that to fulfill TSCA's policy to control chemicals that have been determined to present an "unreasonable risk," limitations imposed by this court decision should be eliminated.[54] Others argue, however, that EPA's capacity under TSCA to promulgate regulations to restrict or ban chemical substances should exist only where such restriction is warranted and EPA can make an "unreasonable risk" determination.

"[W]hile EPA does not contest its obligation to consider whether a proposed action is cost-effective, the court's decision [in *Corrosion Proof Fittings v. EPA*] appears to impose a burden of proof on EPA that significantly increases the level of analysis on potential substitutes and on identifying the least burdensome approach for any future Section 6 actions."[55] In addition to arguments that Congress should overturn the Fifth Circuit's decision on Section 6 standards, it has also been suggested that additional guidance is necessary to define "unreasonable risk." GAO found, for example, that "[w]hile concerns about the potential impact of EPA's regulations on industry are legitimate, the requirement for a finding of unreasonable risk has proven difficult for EPA to implement. TSCA does not define "unreasonable risk" and provides little guidance on what level of risk should be considered unreasonable under the act."[56]

EPA's unsuccessful attempt to ban acrylamide and NMA grout serves as a perfect illustration of the challenges TSCA Section 6 poses. Described as recently as March 20, 2000, by a member of Congress as a "minor Section 6 rulemaking,"[57] EPA has, nonetheless, failed to issue a final rule, despite an Agency effort that spans a decade. EPA's efforts to do so began a full 15 years before 1991, when EPA proposed the ban. The problems that plague this rulemaking provide perhaps an illustration of some of the provisions' key concerns when applied to in-use chemicals.

First, commentors have questioned whether EPA can meet its burden under Section 6(a) regarding the requisite showing of "unreasonable risk." They argue EPA's assessment of the potential risk to workers using acrylamide and NMA grouts employs a series of overly conservative procedures and assumptions to determine the conditions under which the grouts would have no observable neurotoxic effects, and to derive estimates for human exposure and cancer potency. As a result, commentors argue, the approximations of risk are much higher and the margins of exposure are much smaller than are actually likely to be the case.

Second, even if EPA's responding were supported or could be supported, the proposed ban may not be the least burdensome choice to minimize the risk, another requisite showing under TSCA Section 6. Personal protective equipment and other work place safety requirements would, according to grouting industry experts, adequately address any risks posed.

Third, EPA's analysis of potential substitutes for acrylamide and NMA grouts is claimed by some to be inadequate. None of the substitutes has been shown in the rulemaking record to have an efficacy equal to acrylamide and NMA grouts.

Fourth, promulgation of a ban would set a precedent for EPA to use TSCA Section 6 to regulate risks posed solely to workers, despite the fact that TSCA Section 9 appears to preclude such action. Section 9 of TSCA is referred to as the "hand-off" provision. This means that if EPA determines that an unreasonable risk exists with respect to a chemical substance, EPA is required to determine whether the risk can be prevented or reduced "to a sufficient extent by action taken under a federal law not administered by the Administrator [of EPA]."[58] The risks EPA relies upon in proposing to ban acrylamide are purely occupational. Section 9(a), according to some, requires EPA to invite OSHA to address that concern.

These are significant challenges to EPA's proposed rulemaking and help explain a passage of almost a decade since the rule was proposed.[59]

Others argue that the balancing of interests in TSCA Section 6 should not be revised. Balancing interests can, for example, avoid a potentially serious competition problem if other countries do not share the same health and environmental requirements. "Restriction in this country on chemicals for which

there are no economic substitutes will simply transfer—and likely increase—exposures and releases to countries that will not control them nearly as conscientiously as we do."[60] Moreover, limiting risks to "unreasonable" risks were part of the compromise that was reached by Congress during its debate to enact TSCA. As the legislative history provides, Congress compromised on requiring findings of unreasonable risks "because to do otherwise assumes that a risk-free society is attainable, an assumption that the Committee does not make."[61]

TSCA Section 8

Determining whether information is "substantial risk" information under TSCA Section 8(e) has given rise to considerable debate and litigation.[62] EPA has emphasized that "substantial risk" information need not, and most typically does not, establish conclusively that a substantial risk exists. EPA has also said that in deciding whether information is substantial risk information, one must consider the seriousness of the effect, and the fact or probability of the effect's occurrence. The two criteria should be weighed differently, depending upon the seriousness of the effect or the extent of the exposure. In other words, the more serious the effect, the less heavily one should weigh exposure and vice versa. Compliance with TSCA Section 8(e) is complicated by the fact that EPA has never issued regulations examining Section 8(e) and the scope of "substantial risk" information. The most recent guidance EPA has provided was in 1991, when EPA issued its *TSCA Section 8(e) Reporting Guide*.

TSCA Section 9

EPA states that the formal referral system required under TSCA Section 9 "has proven burdensome to EPA and cumbersome as a mechanism for obtaining prompt consideration by applicable agencies."[63] EPA's interpretation that TSCA gives preference to dealing with chemical risks under other laws, such as the CAA and the Occupational Safety and Health (OSH) Act, is considered controversial within and outside the Agency. While recognizing that other laws such as the CAA and the OSH Act can impose limitations on environmental releases and exposures, some argue that TSCA's flexibility to ban or restrict the production, distribution, use, and/or disposal of a chemical substance should not be compromised. According to GAO's report, certain EPA staff, Members of Congress, and environmental groups believe that EPA should pursue more chemical regulations under TSCA.[64]

Changes to TSCA Section 9, however, are considered by others as contravening Congress's intent that TSCA be used to fill regulatory gaps. Robert Hagerman, Dow Chemical Company, stated during the 1994 TSCA hearings CMA's position that TSCA is "a statute fundamentally designed to supplement and support the other environmental or health related statutes."[65]

TSCA Section 14

Much attention has been focused on TSCA's CBI provision. EPA has expressed its dissatisfaction, for example, in its inability to provide states with information on the toxicity and risks of chemical substances used within those states.[66] EPA states further: "there are no costs or disincentives for a company to claim information as confidential business information (CBI); in fact, it is probably less costly to not carefully screen information."[67] Indeed, most environmental groups urge revisions to TSCA's protection of CBI. As Environmental Defense points out: "[I]f a high-volume chemical persists in commercial use without being able to meet minimum screening criteria, for a substantial period of time, the rationale for allowing protection of confidential business information is seriously weakened. The price of maintaining trade secrets about a chemical should be public disclosure of at least the minimum scientific information necessary for safety screening."[68] GAO's 1994 report notes other frustrations with TSCA's CBI provisions. GAO found that "TSCA's CBI provisions are difficult for EPA to implement. Despite EPA's challenges to many CBI claims are not necessary to protect trade secrets, EPA lacks the resources to challenge a significant portion of claims EPA believes to be suspect."[69]

Industry groups have expressed concerns in revising TSCA's CBI provisions. SOCMA states that the chemical industry is highly competitive, and the "maintenance of proprietary information can often make the difference between success and failure."[70] Smith notes further that many companies may determine that if CBI protection cannot be provided, it will not be economically feasible to develop and make new products. As evidence of the highly competitive market, Smith notes that many FOIA requests for such information are submitted by "competitors or law firms working on their behalf."[71]

TSCA Sections 11, 15-17

EPA states TSCA's enforcement provisions and inspection authority need to be strengthened. EPA also notes the decision in *3M Co. v. EPA*, 17 F.3d 1453 (D.C. Cir. 1994), which established a five-year statute of limitations for TSCA administrative civil penalty actions. EPA believes this court decision hampers its enforcement efforts.[72] EPA has also expressed concerns that TSCA does not contain more stringent sanction provisions that are seen in other environmental statutes, including, RCRA and the Clean Water Act (CWA). Moreover, EPA has expressed concern that TSCA does not contain a knowing endangerment provision, as is included in RCRA, the CWA, and the CAA.

Reform Proposals

In addition to examining the problems associated with TSCA as currently written, several solutions and areas for improvement have been offered. Proposed changes involve legislative amendment and reauthorization, as well as improvements through the administrative process. GAO, for example, recommended several legislative changes after concluding in its 1994 report that "TSCA's legal standards for taking regulatory action are so high that EPA has been discouraged from attempting to regulate chemicals and has given implementation of the act a low priority."[73] Below is a synopsis of recommendations from all stakeholders on how TSCA can be reformed.

TSCA Section 4

Several recommendations have been suggested to improve TSCA Section 4. One often repeated recommendation is for Congress to lower the threshold of data requirements for testing under TSCA Section 4. Currently, and as stated above, EPA must find that "there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health and the environment can reasonably be determined or predicted," and "testing of such substance or mixture with respect to such effects is necessary to develop such data." Additionally, EPA must find that the chemical substance is produced in substantial quantities that could result in substantial or significant human exposure or environmental release or presents "an unreasonable risk" to human health or the environment. As EPA stated during the 1994 TSCA reauthorization hearings, "creating a more effective and efficient procedure for promulgating testing requirements would significantly strengthen our ability to obtain priority test data in a reasonable timeframe."

Although TSCA Section 4 speaks of testing "by rule," EPA has developed regulations governing the procedures under which it may decide to enter into ECAs with manufacturers to conduct chemical testing.[74] EPA often prefers such agreements because they avoid the costs and delays associated with notice-and-comment rulemaking. Manufacturers often favor ECAs because EPA regulations permit them to become involved at an early phase, and potentially influence EPA's preliminary testing determinations. EPA will not, however, enter into a consent agreement unless EPA and the manufacturers and processors can reach consensus on the testing requirements and timetable. EPA has stated that TSCA Section 4 could be improved by explicitly recognizing mechanisms such as ECAs and voluntary approaches in the statute.

Several recommendations to improve TSCA Section 4 involve administrative measures. One example that is currently in process and well regarded by many stakeholders is the High Production Volume (HPV) Challenge Program. Recognizing that relatively few TSCA Section 4 test rules or ECAs

have been issued, Environmental Defense, EPA, and CMA conducted reviews in 1997 and 1998 to identify issues relating to the development and dissemination of data. The reports generated by these groups confirmed that toxicity data were not publicly available for a majority of the approximately 2,800 HPV chemicals manufactured or imported in the United States.[75] In response to these findings, and with the cooperation of CMA, EPA created its HPV Challenge Program under which it encouraged chemical manufacturers and importers to conduct testing of chemicals on EPA's list of HPV chemicals, as compiled under the 1990 IUR issued under TSCA. HPV chemicals are defined as those manufactured or imported in quantities exceeding one million pounds.[76]

HPV testing is designed to generate basic toxicity information as defined by the Screening Information Data Set (SIDS) program, developed by the Organization for Economic Cooperation and Development (OECD). That program requires information on basic physical/chemical properties, and approximately 13 studies in the areas of ecotoxicity, environmental fate, and mammalian toxicity. All data produced under the program will be made available to the public. EPA will establish and maintain an electronic database designed to present the data and information in a meaningful and accurate way. For chemicals that are not sponsored under the HPV Challenge Program, EPA will use its TSCA Section 4 rulemaking authority to compel testing. Encouraging and developing voluntary initiatives may solve more problems than legislative changes to TSCA Section 4.

TSCA Section 5

TSCA Section 5's PMN process is one of the pivotal provisions that Congress considered when it enacted TSCA. Congress was interested in filling a "gap" in other statutes by providing for premarket review of new chemical substances. Congress also made clear, however, that "[w]hile the EPA Administrator must be given the authority to act during the premarket notification period to gather more data or to take appropriate restrictive action, the notification burden itself should not be onerous."[77]

Several recommendations have been made for Congress to revise TSCA by placing more of the burden on industry to demonstrate that new chemical substances are safe. GAO recommended, for example, that the burden could be shifted "by requiring industry to test new chemicals and to notify EPA of significant increases in production, releases, and exposures or of significant changes in manufacturing processes and uses after new chemicals enter commerce."[78] Moreover, during the 1994 TSCA Hearings, EPA endorsed a study's findings that EPA's new chemical program "would be strengthened by the ability to obtain test data where SAR techniques are less predictive, a step that would make sense in combination with a move from pre-manufacture to pre-marketing review."[79]

Other approaches to revise TSCA have focused on reviewing the effectiveness of the ways in which other states and countries have controlled chemical substances. Advocates for legislative change have argued that Congress could revise TSCA by implementing successful programs used nationally and internationally. Some of the laws and programs that have been touted as more effective than TSCA, including Section 5, are:

OECD SIDS Program—This program is an international program to obtain screening level data for HPV chemicals.

California's Proposition 65—California voters approved an initiative to address growing concerns about exposures to toxic chemicals in 1986. That initiative became The Safe Drinking Water and Toxic Enforcement Act of 1986, better known by its original name: Proposition 65. Under this law, California is required to publish an annual list of chemicals that are known to the State of California to cause cancer, birth defects, or other reproductive harm. For listed chemicals, businesses are prohibited from knowingly discharging listed chemicals into sources of drinking water; and are required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical. This warning can be given by a variety of means, such as by labeling a consumer product, by posting signs at the workplace, or by publishing

notices in a newspaper. OEHHA notes that "Proposition 65 . . . provides a market-based incentive for manufacturers to remove listed chemicals form their products."[80]

The Canadian Environmental Protection Act—Canada's EPA separates the process of deciding whether to control a chemical from the process of determining what appropriate control action to take. Initially, Canada reviews chemical risks and determines whether a chemical is toxic, defined as "those entering the environment in a quantity or concentration, or under a concentration, having a harmful effect on the environment or human health." If Canada determines a chemical is "toxic," Canada reviews the costs and benefits and determines appropriate control action. Other interest groups, while not advocating making legislative changes to TSCA, do recognize and encourage the need for international cooperation and global acceptance of data developed using any reasonable protocol.

TSCA Section 6

As noted, there is a considerable debate about the legal standard necessary to sustain TSCA Section 6 action. The most often cited recommendation is to ensure that EPA's ability to use TSCA Section 6 is not impeded by the stringent requirements imposed by the courts by urging Congress to amend the "unreasonable risk" standard and the requirement that EPA use the "least burdensome regulation adequate to regulate a substance." GAO, for example, states that Congress could authorize EPA to take control actions when it identifies "significant risks" rather than "unreasonable risks." GAO also states that Congress could revise TSCA's requirement such that EPA need only develop "substantial evidence" to support a regulation.[81]

Other recommendations that could improve TSCA in general, and Section 6 in particular, are for EPA to work on improving its priority setting abilities and the stakeholder process. It is clear that one of the major factors that have hindered EPA's historical implementation of TSCA was the difficulty it faced in setting priorities among possible concerns of chemical substances and mixtures. The need to prioritize better its initiatives is well known to EPA, especially in light of EPA's need to work within budgetary constraints.

TSCA Section 8

The way in which EPA has in recent years expanded its authority under TSCA Section 8 through administrative means demonstrates clearly how EPA can improve TSCA without resorting to legislative amendment. For example, in response to numerous concerns that EPA needed more information on chemical uses and exposure information, EPA proposed amendments to its IUR. Currently, EPA requires under the IUR information on production volume, plant site, and site-limited status of those chemical substances subject to reporting. "Site-limited status" refers to chemical substances at the plant site that are not distributed outside the plant for commercial purposes. Under a rule proposed on August 26, 1999, EPA would expand the information required under the IUR, in part, by adding exposure-related information to the reporting requirements for chemical substances covered by the IUR. EPA states in the proposed rule: "The exposure-related information reported under the IUR amendments, in combination with hazard information such as that developed under TSCA section 4 test rules, would allow the Agency to effectively screen and prioritize chemicals."[82]

Under the current IUR, EPA collects basic production information on approximately 9,000 mostly organic chemicals. Under the proposed amendments, EPA would collect basic production and manufacturing exposure information on approximately 8,900 organic and inorganic chemicals and processing and use exposure information on approximately 4,000 organic chemicals.[83]

EPA also achieved success in obtaining substantial risk information under TSCA Section 8(e) as a result of its one-time compliance audit program (CAP). CAP was developed by EPA in 1991 to correct misinterpretations by industry over what constitutes "substantial risk" information. Companies that agreed to enter CAP were required to audit their files and submit voluntarily all outstanding TSCA Section 8(e) notices. In return, EPA limited the fines to be

imposed against companies that submitted such notices. The fines ranged from $15,000 per study for any submitted study or report involving effects on humans, $6,000 per study for any other study or report submitted, and a one million dollar cap on the possible total civil penalty. The CAP resulted in 123 companies submitting hundreds of TSCA Section 8(e) notices. Eighty-nine of those companies paid a total of $22,000,000 in fines.

TSCA Section 9

Several recommendations have been made to amend TSCA Section 9 to help EPA act quickly and with less difficulty. GAO states, for example, that: "Congress could strengthen EPA's ability to regulate chemicals by allowing TSCA to be used in preference to other environmental laws, when appropriate, and establishing a framework for taking action that is less burdensome for EPA."[84] Others have argued, however, that EPA's general problems in issuing rules under TSCA derive not from TSCA Section 9 concerns, but from lack of coordination between federal agencies, lack of stakeholder involvement, and problems with TSCA funding. SOCMA notes that EPA has in recent years significantly increased its collection of fines through enforcement actions, and "[r]eallocation of some of the enforcement increases to other projects . . . would be far more effective in addressing health and environmental risks."[85]

TSCA Section 14

Environmental groups have different approaches for revising TSCA's CBI provisions.

One revision advocated by EPA and GAO is to increase the dissemination of TSCA data, by providing states with access to confidential data and limited confidentiality claims.[86] At a 1994 hearing before Congress on TSCA, Warren Muir, Hamshire Research Institute, advocated a CBI approach that "includes use-based policies." Under this approach, industry's interest in confidentiality would be respected when its interests are "legitimate," for example, during the research phase of commercial chemical development. CBI protections would not be provided, however, when the chemical is sold or used dispersively, since then "the public need to know about such chemicals weighs much more heavily against any corporate need for trade secrecy."[87] Environmental Defense recommends invalidating trade secret protection "after an appropriate time . . . for any information about a high-volume chemical that has not met screening criteria with publicly available data."[88]

Others argue that any problems associated with TSCA CBI provisions can be fixed administratively. EPA has ample discretion to correct any deficiencies in the law through administrative reform.[89] EPA, for example, held public meetings and obtained public comments on its CBI policies and certain proposed EPA actions that would change CBI requirements. After considering comments on the proposed actions, EPA announced in a July 6, 1994, *Federal Register* notice the availability of its final action plan, which provides various voluntary and regulatory measures to reduce confidentiality claims.

TSCA Sections 11, 15-17

As stated above, EPA seeks to strengthen TSCA's penalties. Specifically, EPA recommends overturning the five-year statute of limitations for TSCA administrative civil penalty actions established in *3M Co. v. EPA*. EPA also recommends: (1) raising sanctions to the same levels currently afforded under RCRA and the CWA; and (2) adding a knowing endangerment provision as is included in RCRA, the CWA, and the CAA and providing EPA with the authority to obtain penalties in a civil judicial forum.

Looking Down the Road

There has been much discussion regarding the future of TSCA and chemical regulation in general. The bottom line is TSCA has served and will continue to serve a vital role in our society. TSCA is a powerful statute and an essential component of U.S. environmental law. Further, toxics reporting laws, the transparency that results from compelled disclosure, and the enhanced availability of chemical testing data through technology will strengthen, not diminish, TSCA's influence in the area of chemical regulation.

Much has happened in the recent past that has helped to define the state of chemical regulation. Two major forces are key among them: transparency/chemical right-to-know and the proliferation of mandatory reporting laws, and technological advances.

With respect to TSCA, the twin forces of transparency and technology have greatly accelerated data production, and heightened the need for accountability, stewardship, and transparency. Technology has greatly accelerated the distribution of test results and the presentation of those results, and hastened the interpretation of those results. These events have made possible collaborative testing initiatives such as the HPV Challenge Program, and voluntary initiatives likely to follow. These initiatives have lessened the need for mandatory Section 4 rulemaking, enhanced stakeholder involvement, and minimized opportunities for government and private sector testing redundancy and inefficiency. At the same time, the very possibility of mandatory Section 4 rulemaking has contributed to the success of the voluntary program. In this regard, TSCA itself has provided a strong incentive to participate in a voluntary testing initiative that is not itself a product of TSCA.

What does the future hold? Based on the foregoing, the future holds the continued expansion of stewardship, accountability, transparency, and volunteerism. There will be a continued urgent need for harmonization in risk screening procedure and test protocol development, and enhanced need for communication strategies, and for the prioritization of testing needs.

These efforts must be taken within a rational framework, however. There is today, perhaps more than ever before, a critical need for a strategy that integrates existing initiatives, regulatory proposals, voluntary initiatives, and current government chemical review processes and resources.

Chemical producers and others are challenged today like never before. Testing initiatives include, among others, the:

- Development of Endocrine Screening Testing Program;
- Children's Health Chemical Testing Program;
- Inventory Update Rule (Aug. 1999);
- Reproductive/Developmental Test Rule;
- Dermal Test Rule;
- HAP Test Rule;
- EPA/CPSC Test Initiative Regarding Certain Chemicals in Kid Products; and
- Office of Pesticide Programs' Stated Intent to Issue a DCI for Inerts, Including Several HPV Chemicals.

In addition, producers must be mindful of other federal agency initiatives, including: the National Toxicology Program's (NTP) testing for cancer potency; NTP/CERHR assessments of selected chemicals' impact on human reproductive/developmental capacity; foreign testing initiatives;[90] and for producers with products in both the industrial and pesticide market, testing is seemingly endless under FIFRA registration, reregistration, tolerance reassessment, and related FQPA initiatives, and EU registration initiatives under EC Directive 91-414.

There are testing challenges at every turn. As a result of these many complex and important testing initiatives, it is all the more important that EPA, with stakeholder involvement, establish testing priorities based on a well-defined strategy, that fairly considers exiting data and that assesses those chemicals first that are likely to pose the greatest potential risk.

A process that enhances stakeholder involvement at virtually every opportunity, fully reflects diverse views and strategic thinking, and ensures greater buy-in and thus minimizes the potential for stakeholder rejection will go a long way at eliminating surprise.

The blueprint for an integrated strategy must fully utilize all existing data sources. All data sources must be considered. For example, TSCATS contains 100,000 unpublished studies. Questions remain, however, whether the data are accessible and searchable. Concurrent federal government testing needs to be rationalized. EPA, NTP, CPSC, and other agencies must understand better what each is doing.

EPA also needs to develop a unified risk screening procedure that reflects relevant existing data. The lack now of an integrated risk screening process hampers the likelihood that future data generating exercises will be predictable and in all cases rational. A unified risk screening process should also be rationalized with global testing initiatives to ensure that the process prioritizes chemical testing based on hazard potency, use, and exposure information.

Finally, everyone needs to spend more time identifying economic incentives for participating in voluntary data generating initiatives. The data compensation provisions under Section 4 of TSCA are of questionable utility on a good day and are inapplicable to voluntary data generating exercises. This is a challenging issue as well under FIFRA, but better defined than it is under TSCA. Compensation for data relied upon by EPA in regulatory contexts might be an option, or tax credits for companies that generate data contributed to EPA and others in voluntary initiatives. Other mechanisms are likely suitable.

Conclusion

TSCA is a vital federal statute. It is EPA's 800 pound gorilla. TSCA has and will continue to serve as a data and information gathering tool that will continue to help identify and define risks posed by chemical exposure. TSCA's goals are greatly enhanced by a new spirit of collaboration made possible in part by EPA's Section 4 authority. This spirit of cooperation will continue to expand as a result of the twin forces of transparency and technology. EPA should consider following the recommendations set forth above and challenge all stakeholders to think of creative economic incentives to enhance participation in voluntary data production initiatives to expand even further the number of voluntary initiatives now in play.

Notes

[1] Public Law 94-469, 90 Stat 2003 *et seq*., 15 U.S.C. 2601 *et seq*.

[2] Three other amendments to TSCA have been enacted since that time: (1) the Asbestos Hazard Emergency Response Act (AHERA), which is now Title II of TSCA, establishing asbestos abatement programs in schools, was enacted in 1986; (2) Title III of TSCA, which was enacted in 1988 and provides for indoor radon abatement; and (3) the Lead-Based Paint Exposure Reduction Act, which is now Title IV of TSCA, was enacted in 1992. TSCA's Title I has not been reauthorized or amended since it was enacted in 1976, however.

[3] Council of Environmental Quality, *Toxic Substances* (Apr. 1971), reprinted in House Comm. On Interstate and Foreign Commerce, 94th Cong., *Legislative History of the Toxic Substances Control Act* 760 (1976).

[4] Chemical substances of particular concern included kepone, "which has been implicated in causing brain damage and other nervous system disorders"; vinyl chloride, arsenic, and asbestos, "all found to be potentially extremely potent cancer-causing agents"; mercury, lead, and other heavy metals; PCBs, "which have been found to cause liver cancer in rats and to have contaminated numerous fish stocks throughout the United States"; and fluorocarbons, propellants in

aerosols and coolants in refrigerators and air-conditioners, suspected of depleting the Earth's ozone layer which protects humans from excessive ultraviolet radiation that can cause skin cancer. S. Rep. 94-698 at 4 (1976), *reprinted in* TSCA Legislative History at 160.

[5] TSCA Section 2(b), 15 U.S.C. § 2601(b)(2).

[6] S. Rep. 94-698 at 1.

[7] S. Rep. 94-698 at 5 ("The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture").

[8] TSCA § 2(b), 15 U.S.C. § 2601(b) (policy to regulate "chemical substances").

[9] TSCA § 3(2)(A), 15 U.S.C. § 2602(2)(A). *See also* 40 C.F.R. § 720.3(e).

[10] Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act; Final Rule, 62 Fed. Reg. 17909, 17911 (Apr. 11, 1997) (to be codified at 40 C.F.R. pts. 700, 720, 721, 723, and 725) (promulgating final rule under TSCA Section 5 to establish notification procedures for review of certain new microorganisms).

[11] *Reauthorization of the Toxic Substances Control Act: Hearing Before the Subcomm. On Toxic Substances, Research and Development of the Senate Comm. on the Environment and Public Works*, 103rd Cong. 46 (1994) (testimony of Lynn R. Goldman, EPA) (1994 TSCA Hearings).

[12] 1994 TSCA Hearings at 48 (testimony of Lynn R. Goldman, EPA).

[13] *See, e.g.*, Ernie Rosenberg and John Wheeler, *TSCA's Successful Balancing Act: Limiting 'Unreasonable Risk' To Health, Environment*, Chemical Regulation Reporter (Nov. 15, 1996) at 1168.

[14] John D. Walker, *The TSCA Interagency Testing Committee, 1977 to 1992: Creation, Structure, Functions and Contributions*, Environmental Toxicology and Risk Assessment: Second Volume, ASTM STP 1216 (1993) at 496.

[15] Walker (1993) at 454.

[16] TSCA § 8(b)(1), 15 U.S.C. § 2607(b)(1).

[17] 40 C.F.R. pt. 720, subpt. C; EPA Form 7710-25.

[18] 40 C.F.R. § 720.50.

[19] *Id.* §§ 720.40(d), 720.3(p).

[20] 1994 TSCA Hearings at 50 (testimony of Lynn R. Goldman, EPA). In 1994, EPA modified its new chemical program by eliminating the requirement that manufacturers and importers submit exemption applications for polymers. The polymer exemption continues to exist for those manufacturers and importers that comply with EPA's extensive reporting and recordkeeping requirements.

[21] 1994 TSCA Hearings at 50 (testimony of Lynn R. Goldman, EPA).

[22] *Id*. at 51.

[23] *Id*.

[24] Because CFCs are now regulated under the Clean Air Act (CAA), EPA revoked its TSCA regulations for CFCs. Chemical Substances; Deletion of Certain Chemical Regulations; Technical Amendments to the Code of Federal Regulations, 60

Fed. Reg. 31917, 31919 (June 19, 1995) (to be codified at 40 C.F.R. pts. 61, 704, 710, 712, 762, 763, 766, 790, 795, 796, 797, 798, and 799) (elimination of Part 762 regulations).

[25] 40 C.F.R. pt. 747.

[26] Asbestos; Friable Asbestos-Containing Materials in Schools; Identification and Notification, 47 Fed. Reg. 23360 (May 27, 1982) (to be codified at 40 C.F.R. pt. 763). When Congress enacted AHERA to address asbestos hazards, however, EPA revoked its TSCA regulations and promulgated regulations implementing the new statute.

[27] 40 C.F.R. pt. 749, subpt. D.

[28] Asbestos; Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions, 54 Fed. Reg. 29460 (July 12, 1989) (to be codified at 40 C.F.R. pt. 763).

[29] *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

[30] *Id*. at 1230.

[31] 56 Fed. Reg. 49863 (Oct. 2, 1991).

[32] Interestingly, on March 20, 2000, the Clinton Administration announced that it is seeking legislative changes that would give EPA the authority under the CAA, not TSCA, to ban methyl tertiary butyl ether (MTBE) as a gasoline additive. Senator James Inhofe, R-OK, was critical of EPA's use of its authority under TSCA Section 6, specifically referring to the acrylamide ban as a "minor Section 6 rulemaking that has taken nearly ten years so far to complete." *BNA Daily Environment Report* (Mar. 21, 2000) at AA-1.

[33] Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, The Environmental Lawyer at 114 (1999).

[34] 63 Fed. Reg. 15765 (Apr. 1, 1998) (revising TSCA Section 8(d) regulations).

[35] These studies are maintained by EPA and published in EPA's TSCATS database. The TSCATS URL is .

[36] 50 Fed. Reg. 27674, 27680 (July 5, 1985).

[37] *Id.* at 27674 (col. 3).

[38] EPA, Enforcement and Compliance Assurance, FY98 Accomplishment Report (June 1999) at 90-92.

[39] *Id*. at 93.

[40] TSCA § 14(a), 15 U.S.C. § 2613(a).

[41] TSCA § 14(a)(1), (2), 15 U.S.C. § 2613(a)(1), (2).

[42] TSCA § 14(a)(3), 15 U.S.C. § 2613(a)(3).

[43] TSCA § 14(a)(4), 15 U.S.C. § 2613(a)(4).

[44] TSCA § 14(d), 15 U.S.C. § 2613(d).

[45] 40 C.F.R. § 2.205(f)(1),(2).

[46] GAO, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective* GAO/RCED-94-103 (Sept. 26, 1994) (GAO Report).

[47] 61 Fed. Reg. 33177 (June 26, 1996).

[48] Importantly, however, of the 21 chemicals proposed for testing, EPA is negotiating with the

producers of approximately half of this number in preparing enforceable consent agreements (ECAs).

[49] 1994 TSCA Hearings at 48 (testimony of Lynn R. Goldman, EPA).

[50] *Id*.

[51] David Roe and William Pease, *Toxic Ignorance*, The Environmental Forum (May/June 1998) at 28.

[52] *Id.* at 27-28.

[53] 1994 TSCA Hearings at 181 (testimony of Hugh M. Smith, SOCMA).

[54] *See, e.g., id.* at 176-177 (testimony of David Monsma, Environmental Action Foundation).

[55] *Id*. at 52 (testimony of Lynn R. Goldman, EPA).

[56] GAO Report at Chapter 2.2.1.

[57] See endnote 33, *supra*.

[58] 15 U.S.C. § 2608(a).

[59] The Office of Management and Budget (OMB) commented extensively on a draft Final Rule in 1995. In response to significant concerns raised by OMB, EPA reopened the rulemaking record in February 1996. 61 Fed. Reg. 7454. For a detailed account of the rulemaking process, *see* Bergeson, L. and L. Campbell. 1998. "Virtual TSCA Bans: The Acrylamide Grout Fiasco." *EPA Admin. L. Rep.* 11(3): 278-283.

[60] Rosenberg and Wheeler at 1167.

[61] H.R. Rep. No. 94-1341, at 15.

[62] *See, e.g.*, EPA, *TSCA Section 8(e) Reporting Guide* (1991) (providing guidance for identifying substantial risk information); letter from V. Kimm, EPA to R. Sussman (Apr. 2, 1992) (clarifying EPA's TSCA Section 8(e) guidance for several toxicological endpoints/observations); 56 Fed. Reg. 4128 (Feb. 1, 1991) (developing a one-time compliance audit program (CAP) for companies that were "misinterpreting" EPA's TSCA Section 8(e) guidance.

[63] 1994 TSCA Hearings at 140 (testimony of Lynn R. Goldman, EPA).

[64] GAO Report at Chapter 0.4.1.

[65] 1994 TSCA Hearings at 155 (testimony of Robert L. Hagerman, Dow Chemical Company).

[66] *See, e.g., id.* at 140 (testimony of Lynn R. Goldman, EPA).

[67] *Id.*

[68] *Toxic Ignorance* at 35.

[69] GAO Report at Chapter 0.3.

[70] 1994 TSCA Hearings at 181 (testimony of Hugh M. Smith, SOCMA).

[71] *Id.*

[72] *Id.* at 140-41 (testimony of Lynn R. Goldman, EPA).

[73] GAO Report at Chapter 0.3.

[74] 40 C.F.R. § 790.22.

[75] Roe, D., Pease, W., Florini, K., and Silbergeld, E., *Toxic Ignorance* (Summer 1997); EPA, Chemical Hazard Data Availability Study (Apr. 1998); CMA, Public Availability of SIDS-Related

Testing Data for U.S. High Production Volume Chemicals (1998).

[76] EPA, Guidance for "What to Test" for the HPV Challenge (Feb. 8, 1999).

[77] S. Rep. 94-698 at 10.

[78] GAO Report at Chapter 3.9.

[79] 1994 TSCA Hearings at 51-52 (testimony of Lynn R. Goldman, EPA).

[80] *See* http://www.oehha.org/prop65.html.

[81] GAO Report at Chapter 2.5.2.

[82] 64 Fed. Reg. 46772, 46775 (Aug. 26, 1999).

[83] EPA, Fact Sheet Proposed IUR Amendments.

[84] GAO Report at Chapter 0.5

[85] 1994 TSCA Hearings (testimony of Hugh Smith, SOCMA).

[86] GAO Report at Chapter 0.5.

[87] 1994 TSCA Hearings at 80 (testimony of Warren Muir, INFORM).

[88] *Toxic Ignorance* at 35.

[89] 1994 TSCA Hearings (testimony of Robert Hagerman, Dow).

[90] For example, Japan announced recently it has identified chemicals that MITI will fund, under the national pollution release and transfer registry, to assess their endocrine disruption potential. Although MITI will fund, it will be important to monitor and participate, as appropriate, in this research.

