The Importance of Implementation in Rethinking Chemicals Management Policies: The Toxic Substances Control Act

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Editors' Summary

Since the passage of the Toxic Substances Control Act in 1976, EPA has struggled with implementation of the law, and with intermittent initiatives has explored, proposed, and attempted solutions to key chemicals management challenges. The successes or failures of TSCA (or any environmental policy for that matter) are not simply an issue of statutory language. Passage of legislation, even well-written and well-intended, is only the first step in successful implementation of a policy. Many other factors, such as political influences, administrative hurdles, and available resources have equal, if not more important, roles in supporting implementation that meets the goals of a particular statute.

There is a long history of federal efforts to manage hazardous industrial chemicals in the United States. Despite these efforts, a chemicals management framework that truly protects public health and the environment, promotes innovation, and provides for the transition to safer chemicals has yet to be achieved. Many critics point to the insufficient provisions of the Toxic Substances Control Act (TSCA)[1] as the source of this outcome.[2] However, this perspective does not tell the whole story. In order to more completely understand TSCA's evolution, statutory, procedural, political, and resource factors involved in the implementation of the law must also be considered.

Since the passage of TSCA in 1976, the U.S. Environmental Protection Agency (EPA) has struggled with implementation of the law, and with intermittent initiatives has explored, proposed, and attempted solutions to key chemicals management challenges. Understanding what has been attempted and why it succeeded or failed provides a new perspective on TSCA's performance and suggests what must be considered to create an effective chemicals management framework. This is particularly important, given ongoing congressional discussions regarding reforms to TSCA.

The purpose of this Article is to highlight the importance of EPA's multiple efforts at implementation in determining the overall effectiveness of TSCA. We take here a systems approach to evaluating the implementation of TSCA that considers the interplay among four critical implementation factors. We take this approach because it offers a wide perspective and allows for the identification and understanding of the many barriers and challenges that must be addressed in developing effective chemicals regulation in the United States. Our intent in this Article is not to critique TSCA or to make recommendations on its future. Rather, by taking a systems approach, we argue that the successes or failures of TSCA (or any environmental policy for that matter) are not simply a matter of statutory language. Passage of legislation, even well-written and well-intended, is only the first step in successful implementation

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1. 15 U.S.C. §§2601-2692, ELR. Stat. TSCA §§2-412.
2. *See* U.S. Government Accountability Office (GAO), Toxic Substances Control Act—Legislative Changes Could Make the Act More Effective (1994) (GAO/RCED-94-103), *available at* http://archive.gao.gov/t2pbat2/152799.pdf; Richard A. Denison, *Ten Essential Elements in TSCA Reform*, 39 ELR 10020 (Jan. 2009), *available at* http://www.edf.org/documents/9279_Denison_10_Elements_TSCA_Reform.pdf; Joel A. Tickner, The Promise and Limits of the United States Toxic Substances Control Act (Oct. 10, 2003), http://www.chemicalspolicy.org/downloads/10-03_Chemicals_Policy_TSCA.pdf.

of a policy. Many other factors, such as political influences, administrative hurdles, and available resources have equal, if not more important, roles in supporting implementation that meets the goals of a particular statute.

The first section of this Article presents a brief introduction to TSCA. The second identifies and defines factors shaping the implementation of TSCA. The third section illustrates EPA's implementation efforts with regards to four chemicals management challenges, including prioritizing chemicals of concern, establishing a minimum chemical data set for new and existing chemicals, taking appropriate and timely action on chemicals, and providing access to chemical information. The final section of the Article analyzes the role statutory, procedural, political, and resource factors played in the implementation of TSCA, highlighting specific examples from EPA's efforts on key chemicals management challenges. In the Article, we focus primarily on understanding the historical implementation of TSCA through the early 1990s. While additional programs and efforts at implementation of TSCA have occurred since that period, in particular since 2009, we believe that the first 15 years of TSCA's implementation provide critical lessons for the design of future policies.

I. An Introduction to TSCA

In 1971, the Council on Environmental Quality (CEQ) released an influential report detailing the problems caused by toxic chemicals in the United States and highlighting the need for regulation.[3] The U.S. Congress enacted TSCA after five years of public hearings and debate. The statute's ambitious regulatory agenda created high expectations for improvements in chemicals regulation and management. TSCA promised to: (1) create an inventory of existing chemicals and require the premanufacture review of any chemical not included on this inventory; (2) require chemical manufacturers and processors to develop data on the health and environmental effects of their chemicals; and (3) restrict or require labeling on chemicals that present unreasonable risks.

Although TSCA gave EPA broad authority and many tools to move forward on chemicals regulation, much of the regulatory agenda outlined in 1976 remains undone after nearly 35 years of implementation. It is instructive to review the implementation process of TSCA to understand how this happened.

II. Factors Shaping the Implementation of TSCA

As the history of TSCA illustrates, implementation factors determine whether policy goals may or may not be achieved. Although the language of the law itself plays an important role in implementation, much of what happens in the implementation process cannot be explained solely by the intentions and directions of the drafting policymakers. Implementation is best understood by examining the context within which implementation proceeds, as "each policy has its own legislative, administrative, and political legacy and current culture that determines, in large and small ways, the rate and progress of implementation."[4]

This Article examines four factors—statutory language, procedural framework, political context, and resources—that strongly affect and shape the implementation and outcomes of a chemicals policy like TSCA. These factors are detailed in turn.

Statutory language is a critical factor in determining the implementation of a chemicals policy. Clear mandates, realistic timetables, and statutory limitations placed on delegated authority within the law serve to shape policy development.

The *procedural framework* is a second major factor affecting implementation. The rulemaking process, judicial review, burdens of proof, and the handling of confidential business information (CBI) all play important roles in the development of a chemicals policy.

A third factor that affects the implementation of a chemicals policy is the *political context*. This includes the vision and leadership in the implementing agency, the presence of congressional champions and oversight, the competing priorities in the implementing agency, jurisdictional struggles, new regulatory challenges, and the presence and intensity of interest group involvement.

Finally, *available resources* are a fourth factor affecting chemicals policy implementation. The availability of both fiscal resources and human resources at the time the law is passed and the changes that occur to these resources over time alter the implementation of a chemicals policy.

Ultimately, it is the interplay of all four of these factors that results in the success or failure of a chemicals policy. We graphically depict the interplay between these factors in a systems map in Figure 1. The graphic shows that these four factors should not just be construed as individual influences on TSCA implementation, but rather as a system of interconnected influences. It illustrates how each factor not only affects implementation in its own ways, but also how the various factors influence each other. Given this interplay, it is difficult and overly simplistic to state the relative importance of one factor versus another in TSCA's implementation.

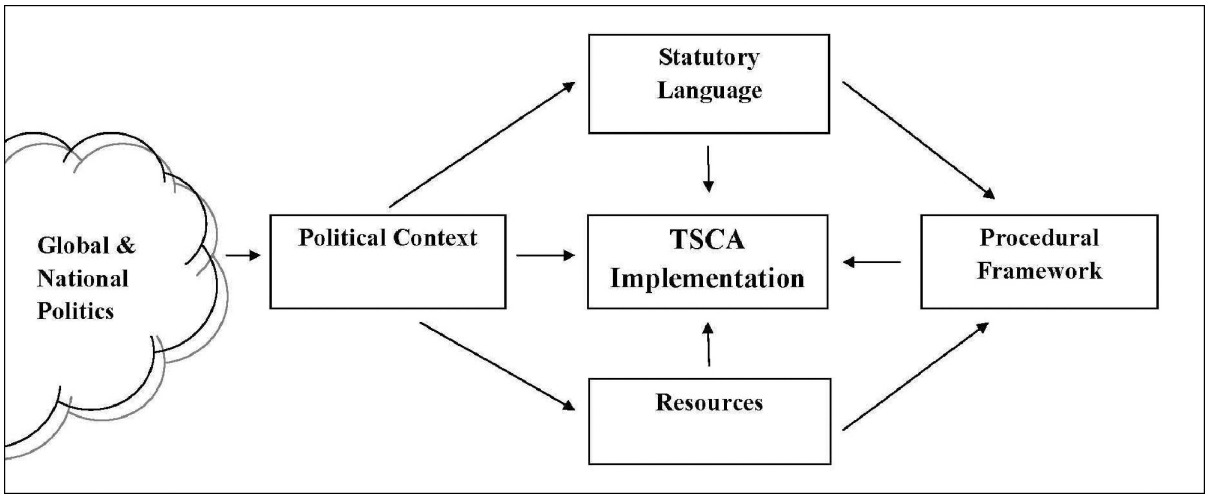
III. EPA's Implementation Efforts—Attempts to Solve Key Chemicals Management Challenges

Before analyzing the four factors that shaped TSCA implementation, it is useful to examine four chemicals management challenges that are critical to the regulatory agenda

3. CEQ, Toxic Substances (Apr. 1971), *reprinted in* House Comm. on Interstate and Foreign Commerce, 94th Cong., Legislative History of the Toxic Substances Control Act, at 757-88 (1976).

4. Denise Scheberle, Federalism and Environmental Policy: Trust and the Politics of Implementation 26 (1st ed. 1997).

Figure 1: Factors Shaping the Implementation of TSCA



of TSCA and have persisted throughout TSCA's nearly 40-year history. The challenges include: (1) prioritizing chemicals of concern; (2) establishing a minimum chemical data set for new and existing chemicals; (3) providing access to chemical information; and (4) taking appropriate and timely action on chemicals.

By detailing EPA's attempts to address these four challenges, we are able to recognize EPA's innovative implementation efforts, acknowledge the limits of those efforts, and lay the foundation for understanding how these efforts were influenced by a range of statutory, procedural, political, and resource forces external and internal to the Agency.

A. Prioritizing Chemicals of Concern

Starting from the days shortly following passage of TSCA, EPA struggled to develop and implement a number of priority-setting methodologies and systems for addressing existing chemicals. Every several years, EPA changed direction with regards to priority-setting. For example:

- In 1977, the TSCA Interagency Testing Committee, charged with recommending chemicals for which further testing should be required by EPA, developed a two-stage methodology for prioritizing chemicals. The first stage rated chemicals based on their degree of human and environmental exposure and the second stage scored chemicals based on seven different human health and ecological effects.[5]
- In 1978, EPA detailed the working decisions emphasized in setting priorities and described the development of a multi-stage process for identifying substances of priority concern. This new process included the selection of chemicals, using readily available data, on the basis of structure/activity correlations, biological activity, production volume, potential for environmental release and exposure, and persistence.[6]
- In 1982, EPA's Existing Chemicals Task Force conducted reviews of existing substances identified by selecting chemicals for which: (1) test data were received under §4; (2) substantial risk notices were received under §8(e); (3) test data were received from other reputable sources, such as the National Toxicology Program; or (4) concerns were consistently raised during the new chemicals Pre-Manufacturing Notice (PMN)[7] reviews.[8]
- In 1983, EPA launched efforts to select existing chemicals for evaluation by "cluster" analysis, a priority-setting system that would assign aggregate measures of risk to categories of chemicals with similar uses or structures.[9]
- In 1991, EPA screened existing chemicals using a tiered risk management process with two levels of review. Risk Management 1 (RM1) was designed to screen and select those chemicals likely to be of greatest concern to human health and the environment. Risk Management 2 (RM2) investigated and analyzed chemicals identified in RM1 and framed options for reducing or eliminating the risk they posed.[10]
- In 1994, EPA launched the Use Clusters Scoring System, a chemical ranking and scoring methodology

5. J. Clarence Davies et al., Determining Unreasonable Risk Under the Toxic Substances Control Act 2 (1979); TSCA Interagency Testing Committee—Initial Report to the Administrator, Environmental Protection Agency, 42 Fed. Reg. 55036-48 (Oct. 12, 1977).
6. Toxic Substances Control—Proposed Approach to Implementing the Toxic Substances Control Act, Request for Public Comment, 43 Fed. Reg. 50140 (Oct. 26, 1978).
7. Under §5 of TSCA, manufacturers or importers are required to notify EPA (providing specific chemical, company, and process information) prior to introducing a new chemical into commerce.
8. U.S. EPA, TSCA Priorities and Progress 23 (July 1983).
9. *Id.* add. 8 (July 1983).
10. U.S. EPA, *Process to Review Existing Chemicals Shows Results*, Chemicals in Progress Bulletin, Aug. 1991, at 6-9; U.S. EPA, Annual Report of the Office of Pollution Prevention and Toxics FY 1995 (Sept. 1996), http://www.epa.gov/opptintr/ar95/opptindx.htm.

based around the creation of chemical "use clusters," a set of competing chemicals and technologies for a given functional use (e.g., adhesives, coloring agents, intermediates, solvents, etc.).[11]

- In 2007, under the Chemical Assessment and Management Program (ChAMP), EPA developed a system of risk-based prioritization for high-production volume chemicals and hazard-based prioritization for moderate-production volume chemicals.[12]
- In 2009, EPA announced the development of chemical action plans, based on EPA's review of available hazard, exposure, and use information, to target risk management efforts on chemicals of concern.[13]

As the above efforts illustrate, the priority-setting process for existing chemicals changed often throughout the implementation of TSCA. EPA made repeated and differing attempts at identifying priority candidates from the large number of existing chemicals, relying on different prioritization methods at various times.

B. Establishing a Minimum Chemical Data Set for New and Existing Chemicals

As EPA noted in 1977, "information is the lifeblood of the overall system. Early development of policies and procedures to establish a broadly based and technically sound data base, drawing on domestic and foreign sources and readily accessible to all interested parties, is essential if future regulatory actions are to be soundly conceived."[14]

Despite high expectations for data development and collection under TSCA, early EPA efforts to collect and develop data from industry were based on the concept of "selectivity," that is to say approaching data collection through testing requirements on suspect chemicals rather than broad-based screening requirements on as many chemicals as possible. EPA also developed hierarchical schemes for testing, which consisted of several levels or tiers involving progressively more detailed and expensive testing procedures, with the decision to conduct further testing dependent on the development of certain baseline data. Overall, EPA's early approach to data collection amounted to gathering data "on a highly selective basis to serve specific purposes."[15]

Although EPA attempted to identify minimum toxicity data requirements and develop minimum data requirements for chemicals during the late 1970s, these approaches were never fully implemented.[16] Instead, for existing chemicals, formal test rules were promulgated on a largely chemical-by-chemical basis to develop toxicity (human health and environmental effects) information for chemicals of concern. During the early 1980s, near the beginning of EPA's implementation of this program, EPA began to rely substantially on voluntary testing agreements. EPA negotiated these voluntary agreements individually with the manufacturers of the chemicals to be tested, rather than issue test rules to collect toxicity information on existing chemicals.[17]

EPA also attempted to gather chemical use and exposure information through the development of tiered reporting rules, presenting a progression of increasingly detailed reporting requirements.[18] This effort culminated in the promulgation of two model rules: the Preliminary Assessment Information Rule (PAIR) and the Comprehensive Assessment Information Rule (CAIR).[19] The final PAIR rule required chemical manufacturers to submit information on approximately 250 chemicals, which included data on: the quantities of chemicals manufactured; the amount directed to certain classes of uses; and the potential exposures and environmental releases associated with processing.[20] To date, EPA has required PAIR reporting for 1,200 chemicals.[21] The final CAIR rule required reporting on 19 chemicals, which included data on: plant site information; chemical identification; production, processing, and importation volumes; physical/chemical properties; environmental fate data; economic and financial information; manufacturing and processing information; waste generation and management; worker exposure; and environmental release.[22]

Additionally, EPA made efforts to collect screening-level, exposure, and use-related information on chemical substances so that the Agency could determine quickly, accurately, and efficiently who produces certain chemical substances, where they are produced, and in what quantities. In order to overcome the lack of readily available production data and the resource-intensive, inefficient manner of collecting this type of information,[23] EPA promulgated the Inventory Update Rule (IUR) in 1986, which required

11. U.S. EPA, Chemical Use Clusters Scoring Methodology (Apr. 13, 1993).
12. U.S. EPA Chemical Assessment and Management Program (ChAMP), http://www.epa.gov/ChAMP/ (last visited Apr. 17, 2011).
13. U.S. EPA, Existing Chemical Action Plans, http://www.epa.gov/opptintr/existingchemicals/pubs/ecactionpln.html (last visited Apr. 17, 2011).
14. U.S. EPA, Assessment and Control of Chemical Problems: An Approach to Implementing the Toxic Substances Control Act (Feb. 17, 1977) (unpublished document, on file with author).
15. *Id.*
16. *Id.*; U.S. EPA, Health Effects Guidelines—Section 5 (Sept. 8, 1978) (unpublished document, on file with author).
17. *Implementation of the Toxic Substances Control Act Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the S. Comm. on Environment and Public Works*, 97th Cong. (1982).
18. Pesticides and Toxic Substances—General Recordkeeping and Reporting Requirement: Preliminary Assessment Rule, 45 Fed. Reg. 13646 (Feb. 29, 1980).
19. Chemical Information Rules—Manufacturers Reporting, Preliminary Assessment Information, 47 Fed. Reg. 26992 (June 22, 1982); Proposed Comprehensive Assessment Information Rule, 51 Fed. Reg. 35761 (Oct. 7, 1986).
20. Chemical Information Rules—Manufacturers Reporting, *supra* note 19.
21. E-mail from Brian Symmes, Deputy Director of the National Program Chemical Division, Office of Chemical Safety and Pollution Prevention, U.S. EPA, to Jessica Schifano, Policy Analyst, Lowell Center for Sustainable Production (Dec. 14, 2010) (on file with author).
22. Comprehensive Assessment Information Rule, 53 Fed. Reg. 51698 (Dec. 22, 1988).
23. Partial Updating of TSCA Inventory Database—Production and Site Reports, 50 Fed. Reg. 9944 (Mar. 12, 1985).

manufacturers and importers to initially and periodically (every four years) report data on the production volume, plant site, and site-limited status for certain chemical substances produced in quantities over 10,000 pounds.[24] In 2003 and 2005, EPA amended the IUR to expand the range of reporting required under the rule and extend the period of reporting,[25] and on August 13, 2010, EPA proposed additional changes to the IUR reporting requirements that would allow for additional product-use level chemical data.[26]

Despite these efforts, substantial data gaps persisted. In 1997, the Environmental Defense Fund published an influential report detailing EPA's failure to collect even basic toxicity information on the highest production volume chemicals in commerce in the United States.[27] A 1998 report by EPA also described the lack of data on high-production volume chemicals, finding that 43% of these chemicals had no testing data on basic toxicity and only 7% had a full set of basic test data.[28] As a response to these widely publicized data gaps, EPA initiated the High Production Volume (HPV) Challenge Program in 1998. In this voluntary initiative, chemical manufacturers and importers agreed to sponsor and collect basic hazard data for HPV chemicals. As of 2007, companies have sponsored more than 2,200 HPV chemicals. However, 267 "orphan" HPV chemicals remain unsponsored.[29]

For new chemicals, EPA attempted early on to develop internal guidance on minimum data requirements for the new chemicals review process based on chemical categorization considerations, with data requirements varying among categories.[30] Additionally, as part of the required PMN submissions, EPA initially gave much consideration to developing recommended testing guidelines for all new chemicals.[31] Although testing guidelines for all new chemicals were never finalized, in 1981, EPA published a policy statement that recommended that chemical producers develop the Minimum Premarket Data set defined by the international Organization for Economic Cooperation and Development (OECD).[32] In 1988, EPA implemented a policy to establish testing requirements for new chemicals based on potential for substantial production or environmental or human exposure.[33] The Agency also solidified minimum testing guidelines for specific categories of chemicals of concern,[34] which remain in effect today.[35]

EPA participated in work undertaken by the OECD Chemicals Group, under the supervision of the OECD Environment Committee, to develop a Minimum Pre-Marketing Set of Data (MPD) for new chemicals. This effort attempted to identify principles and criteria for determining when various tests should be performed. In May 1980, the First High Level Meeting of the Chemicals Group endorsed the MPD, with full support from U.S. representatives.[36] The Environment Committee endorsed the MPD and recommended it to the OECD Council in 1981. However, in the face of U.S. opposition under the new administration, the Council failed to enact either a decision or a recommendation concerning MPD.[37] In 1982, the Council did make a decision on MPD, but added an interpretive statement that permitted member countries to omit or substitute certain tests or ask for them in a later stage of initial assessment and, in no way, bound the United States to incorporate the MPD into its implementation of TSCA.[38]

Ultimately, despite EPA's broad authority to collect and require the development of data, the Agency never established minimum chemical data sets for new or existing chemicals.

C. Providing Access to Chemical Information

Over the years, EPA has struggled with the challenge of protecting legitimate claims to CBI while advancing the goals of the Act. Unique for most statutes that EPA administers, TSCA regulates the production of chemicals and chemical products, materials, and production technologies, making the regulated community protective of information that may jeopardize a competitive advantage. During the early implementation of TSCA, EPA noted that "assertions of trade secrecy and related confidential-

24. Partial Updating of TSCA Inventory Database—Product and Site Reports, Final Rule, 51 Fed. Reg. 21438 (June 12, 1986).
25. U.S. EPA, Inventory Update Reporting (IUR), http://www.epa.gov/iur/pubs/guidance/basic.html (last visited Apr. 20, 2011).
26. U.S. EPA, Inventory Update Reporting (IUR)—About Submissions, http://www.epa.gov/iur/pubs/guidance/aboutsub.html (last visited Apr. 20, 2011).
27. *See* Environmental Defense Fund, Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States (1997), http://www.edf.org/documents/243_toxicignorance.pdf.
28. U.S. EPA, Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals? (1998), http://www.epa.gov/hpv/pubs/general/hazchem.pdf.
29. U.S. EPA, High Production Volume (HPV) Challenge, http://www.epa.gov/hpv/pubs/general/basicinfo.htm (last visited Apr. 17, 2011).
30. U.S. EPA, Assessment and Control of Chemical Problems: An Approach to Implementing the Toxic Substances Control Act (Feb. 17, 1977) (unpublished document, on file with author).
31. Steven D. Jellinek, Assistant Administrator for Toxic Substances, U.S. EPA, Remarks Before the Midland Section of the American Chemical Society, TSCA Two Years After: Taking Stock (Nov. 4, 1978).
32. New Chemical Substances—Premanufacture Testing Policy, 46 Fed. Reg. 8986 (Jan. 27, 1981).
33. U.S. EPA, *Testing for New Chemicals Based on Exposure*, Chemicals in Progress Bulletin, June 1988, at 10.
34. *See* U.S. EPA, Chemical Manufacturers Association (CMA) Letter, http://www.epa.gov/oppt/newchems/pubs/cmaxpltr.htm (last visited Apr. 17, 2011).
35. U.S. EPA, TSCA New Chemicals Program (NCP) Chemical Categories (2010), http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf.
36. Organization for Economic Cooperation and Development (OECD), *OECD Minimum Pre-Marketing Set of Data*, OECD Doc. ENV/CHEM/HLM/80.1 (Apr. 11, 1980), *reprinted in* 19 Int'l Legal Materials 1072-82 (1980).
37. Blake A. Biles, *Harmonizing the Regulation of New Chemicals in the United States and in the European Economic Community*, *in* TSCA's Impact on Society and Chemical Industry 52 (George W. Ingle ed., 1983).
38. OECD, *Council Decision Concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals*, OECD Doc. C(82)(196) (Dec. 8, 1982), *reprinted in* 22 Int'l Legal Materials 909 (1983).

ity matters could cause many implementation problems and must be addressed promptly."[39] Such implementation problems might include diversion of staff resources from chemical management activities, and limiting the ability of other federal and state agencies and the public to take appropriate preventive actions.

In an effort to address these problems, EPA described its policy for the submission and review of confidentiality claims with regards to submissions to the TSCA Inventory in 1978. The policy required any submitter claiming confidentiality for a chemical identity to answer detailed questions on the adverse competitive effect of disclosure, the precautions taken to prevent disclosure, and other items. Manufacturers were permitted to claim confidentiality for data such as the company name, site, and production quantities, with substantiation required at the time the information was submitted. In addition, EPA created a critical review and challenge process for these claims, especially confidentiality claims for chemical identity.[40]

EPA also struggled with claims of CBI in its implementation of the PMN provisions of §5 of TSCA. In 1980, EPA issued a Statement of Revised Interim Policy for submission of PMNs that encouraged submitters to substantiate all claims of confidentiality at the time of submission. If confidentiality claims were not substantiated at the time of submission, EPA stated that it would send the submitter a letter requesting substantiation. However, due to industry pressure, in 1982, EPA determined that it would no longer routinely request substantiation of all confidentiality claims in PMNs and would require substantiation only after receiving a request under the Freedom of Information Act (FOIA). Confidentiality claims for chemical identity were required to be substantiated at the time a notice of commencement of manufacture or import was submitted.[41] This policy change was confirmed in the Final PMN Rule published during 1983.[42] Ultimately, this change resulted in a significant increase in the proportion of PMN submissions affected by CBI claims, relative to the preceding three years.[43]

Due to continuing struggles with the large and increasing volume of CBI claims,[44] EPA released a Proposed Action Plan for CBI Reform in 1993,[45] which the Agency finalized the next year.[46] The plan identified short- and long-term "action items" that EPA believed would address the problems with CBI policy, which included the following:

- Reviewing and amending regulations and policy statements on CBI filings;
- Continuing the CBI Review Program for §§8(d) and 8(e) health and safety submissions;
- Establishing reassertion or resubstantiation provisions;
- Initiating voluntary education efforts by industry groups to educate companies about CBI practices;
- Requiring senior management officials to certify CBI claims; and
- Requiring up-front substantiation of CBI claims.[47]

As a result of these efforts, EPA began a systematic review of CBI claims submitted under TSCA and conducted extensive outreach efforts to educate industry about CBI practices. EPA also published a proposed rule to supplement its TSCA CBI regulations in November 1994.[48] The proposed rule addressed several action items from the Final Action Plan, such as up-front substantiation of confidentiality claims and sunset provisions, and clarified the meaning of "health and safety" studies in §14(b). The Office of Management and Budget (OMB) disapproved of the proposed rule in 1995,[49] and the proposal was withdrawn in 2000.[50]

At the time the 1994 proposal was withdrawn, EPA initiated a new and separate rulemaking effort for the reform of CBI regulations. The new rulemaking included the up-front substantiation of CBI claims, but omitted all of the other proposals in the 1994 Action Plan and proposed rule.[51] This proposed rule was never finalized by the Agency.

Over time, EPA also made a number of attempts to strengthen CBI rules for various submissions under TSCA. EPA attempted to tighten the CBI rules during the 1990s for PMN submissions[52] and succeeded in tightening the CBI rules in 2003 for submissions under §8(e)[53] and in 2005 for submissions under the Inventory Update Rule.[54]

Currently, EPA has renewed its focus on reforming its CBI policy. On January 21, 2010, EPA issued a new policy

39. U.S. EPA, Assessment and Control of Chemical Problems: An Approach to Implementing the Toxic Substances Control Act (Feb. 17, 1977) (unpublished document, on file with author).
40. Toxic Substances Control—Proposed Approach to Implementing the Toxic Substances Control Act, Request for Public Comment, 43 Fed. Reg. 50140 (Oct. 26, 1978).
41. Premanufacture Notices—Substantiation of Confidentiality Claims, 47 Fed. Reg. 28969 (July 2, 1982).
42. Premanufacture Notification—Premanufacture Notice Requirements and Review Procedures, 48 Fed. Reg. 21722 (May 13, 1983).
43. Sheila A. Ferguson et al., Influence of CBI Requirements on TSCA Implementation (1992).
44. *Id.*
45. U.S. EPA, Proposed Actions to Reform TSCA Confidential Business Information (May 20, 1993).
46. U.S. EPA, Final Action Plan: TSCA Confidential Business Information Reform (June 20, 1994).
47. *See* U.S. EPA, Proposed Actions to Reform TSCA Confidential Business Information, *supra* note 45; U.S. EPA, Final Action Plan: TSCA Confidential Business Information Reform, *supra* note 46.
48. Public Information and Confidentiality Regulations, 59 Fed. Reg. 60446 (Nov. 23, 1994).
49. Agency Information Collection Activities Under OMB Review, 60 Fed. Reg. 15564 (Mar. 24, 1995).
50. Public Information and Confidentiality—Advance Notice of Proposed Rulemaking, Withdrawal of 1994 Proposed Rule, 65 Fed. Reg. 80394 (Dec. 21, 2000).
51. *Id.*
52. *See* Premanufacture Notification—Revisions of Premanufacture Notification Regulations, Proposed Rule, 58 Fed. Reg. 7661 (Feb. 8, 1993); Premanufacture Notification—Revisions of Premanufacture Notification Regulations, Final Rule, 60 Fed. Reg. 16298 (Mar. 29, 1995).
53. TSCA §8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33129 (June 3, 2003).
54. TSCA Inventory Update Reporting Revisions, 70 Fed. Reg. 75059 (Dec. 19, 2005).

to increase the public's access to information on the potential risks posed by chemicals. Under this policy, EPA plans to reject certain types of confidentiality claims for chemical identity in health and safety studies.[55] On May 27, 2010, EPA announced the Agency's plan to review confidentiality claims for chemical identities and data from health and safety studies for both newly submitted and existing claims beginning on August 25, 2010.[56] In its strategic plan issued on September 30, 2010, EPA committed to review and, where appropriate, to challenge and declassify CBI claims for hundreds of annual new submissions and more than 20,000 previous submissions.[57]

Overall, EPA made multiple attempts to manage CBI so as to eliminate barriers to the effective implementation of TSCA's authorities. However, these attempts often fell short practically, and CBI has remained a barrier to TSCA implementation.

D. Taking Appropriate and Timely Action on Chemicals

TSCA provides EPA with a suite of regulatory options for taking action on problematic chemicals, which includes: banning or limiting manufacture, processing, distribution, or use of a chemical; requiring warning labels; requiring specified disposal methods; requiring specified quality-control measures during the manufacturing process; and gathering and requiring the development of information on chemicals. As EPA noted in 1978, "TSCA's authority extends to every facet of the chemical industry from research and product development, test marketing, manufacturing, processing, distribution, use, and disposal."[58]

In order to exercise this authority, EPA has the burden of demonstrating that an unreasonable risk exists, demonstrating that the regulatory action chosen is the least burdensome reasonable regulation, and developing substantial evidence to withstand judicial review, including cost-benefit balancing.

During the early years of TSCA implementation, EPA struggled to define "unreasonable risk," as Congress failed to specifically define this term in the law. An EPA internal memo sets out a range of operational approaches to determining when risks should trigger TSCA action.[59] However, EPA did not aggressively apply any of these approaches to the universe of new and existing chemicals.

Instead, EPA utilized its authority to undertake a number of very specific regulatory actions on a small number of new and existing chemicals. For example, EPA successfully banned nonessential uses of chlorofluorocarbons (CFCs) as propellants in aerosol spray cans (1978); prevented the land disposal of one kind of dioxin by one manufacturer (1980); required all public and private elementary and secondary schools to inspect for friable asbestos-containing materials (1982); prohibited the addition of any nitrosating agent to metalworking fluid containing mixed mono and diamides of an organic acid, triethanolamine salts, triethanolamine salt of tricarboxylic acid, and tricarboxylic acid (1984); and restricted the use of hexavalent-chromium-based water treatment chemicals in commercial cooling towers (1990). During this time, EPA also made referrals regarding existing chemicals to other agencies, such as the Occupational Safety and Health Administration (OSHA) and the Federal Food and Drug Agency (FDA), for action.[60]

Despite some successes, EPA ultimately failed to broadly ban all uses of even one existing chemical (polychlorinated biphenyls (PCBs) were banned in the original statute). EPA attempted to refer asbestos to OSHA for action; however, Congress and public interest groups objected, and the Agency issued a final rule in July 1989 to ban the manufacturing, importing, and processing of nearly all asbestos products. EPA was challenged in federal court by asbestos manufacturers, and in October 1991, the U.S. Court of Appeals for the Fifth Circuit vacated most of the rule and remanded it to the Agency for further consideration. 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. The court's analysis and conclusions suggest that the "least burdensome alternative" requirement was the key factor in its decision to overturn the asbestos rule. 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."[61]

Although some additional attempts were made to regulate existing chemicals, such as a ban on acrylamide and N-methylacrylamide grouts (1991) and lead fishing sinkers (1994), regulations were never finalized.

Due to ongoing frustrations in attempts to exercise its regulatory authority and the passage of the Pollution Prevention Act (PPA) in 1990, EPA began to move away from focusing on rule development under TSCA and began to apply a vision of prevention, substitution, and voluntary

55. Claims of Confidentiality of Certain Chemical Identities Submitted Under Section 8(e) of the Toxic Substances Control Act, 75 Fed. Reg. 3462 (Jan. 21, 2010).
56. Claims of Confidentiality of Certain Chemical Identities Contained in Health and Safety Studies and Data From Health and Safety Studies Submitted Under the Toxic Substances Control Act, 75 Fed. Reg. 29754 (May 27, 2010).
57. U.S. EPA, FY2011-FY2015 EPA Strategic Plan 2 (2010).
58. U.S. EPA, TSCA Revised Strategy: Discussion Draft for the Toxic Substances Priorities Committee (Aug. 14, 1978) (unpublished document, on file with author).
59. U.S. EPA, The Approach to Unreasonable Risk (undated) (unpublished document, on file with author).
60. U.S. GAO, Toxic Substances Control Act—Legislative Changes Could Make the Act More Effective (1994) (GAO/RCED-94-103), *available at* http://archive.gao.gov/t2pbat2/152799.pdf.
61. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 22 ELR 20304 (5th Cir. 1991).

engagement of chemical users and technology developers to move toward safer chemicals.[62]

Despite historical difficulties in exercising its regulatory authority under TSCA, EPA initiated a comprehensive approach to enhance the Agency's current chemicals management program in 2009. These new efforts include some creative uses of the existing TSCA regulatory and nonregulatory tools to take action on a number of chemicals, such as lead, mercury, formaldehyde, PCBs, glymes, and nanomaterials, as well as the development of chemical action plans for several chemicals of high concern.[63] These efforts to creatively utilize TSCA authorities are occurring against a backdrop of TSCA reform activities in Congress.

IV. A Systems View of TSCA Implementation

In this section, we analyze how statutory, procedural, political, and resource factors, and the interactions between them, influenced EPA's implementation of TSCA, highlighting particular examples from the four chemicals management challenges outlined above. This systems approach offers a broad perspective and allows for the identification and understanding of the interconnected nature of the many barriers and challenges to implementation.

A. Statutory Language

Statutory language itself plays a key role in policy implementation. Although most critics have focused on the lack of authority in TSCA to explain its shortcomings, the barriers to implementation arising from the statutory language go beyond simple questions of authority. The absence of clear mandates and realistic timetables, as well as the presence of limitations on the broad authority granted to EPA within the law, have all influenced TSCA implementation.

While broad policy goals are enumerated in the statute, with few exceptions, there is very little language mandating EPA to take actions necessary to achieve these goals. Instead, TSCA provides EPA with expansive authority to collect information, regulate chemicals, and review new chemicals before manufacture, but provides little guidance on where to begin and no schedule for moving forward. As then-Assistant Administrator for the Office of Pollution Prevention and Toxics, Linda Fisher, explained in 1992, "one of the problems, in a sense, with the statute is it is replete with tremendous flexibility and very little guidance on where to start and what to do first. In a sense, I think that has confounded the TSCA program."[64] This is especially true for TSCA's approach to existing chemicals.

Even where TSCA enunciates a broad goal, the goal alone is not enough to spur the effective implementation of the authorities designed to fulfill the statute's vision. This is illustrated by the goals laid out in the statute with regards to data collection. President Richard M. Nixon, at the time of introducing TSCA in 1971, "propose[d] that the Administrator be authorized to prescribe minimum standard tests to be performed on substances."[65] This objective was formalized in TSCA §2(b), which provides that adequate data on the effects of chemical substances should be developed as the responsibility of those who manufacture and process them. Despite this broad vision (and subsequent authorities) to collect chemical data, major data gaps still exist.

Despite the broad authorities given to EPA under TSCA, Congress limited that ability to act to chemicals that present an "unreasonable risk." Congress mandated that actions under a number of TSCA provisions be triggered by determinations concerning the actual or potential risk to health or the environment. In some instances, the term "unreasonable risk" is used, in one case "substantial risk" is used, and in other cases, elaborations of unreasonable risk, such as "may present" or "will present" are used.[66] Although this limitation was set out in the law, Congress failed to specifically define the term "unreasonable risk." Because of the standard's prominent role in modulating EPA authority in a number of respects, early TSCA commentators described the unreasonable risk standard as the crux of the law, stating "the term is so central to the Act that the way it is interpreted by EPA and the courts will determine the impact and effectiveness of TSCA."[67]

Throughout TSCA implementation, "unreasonable risk" has been interpreted by EPA and the courts in a number of different ways. For example, the courts have broadly construed the term with regards to EPA's authority to impose testing requirements under §4, in part due to the qualifier "may".[68] On the other hand, the courts have determined the standard to be very high in cases where EPA attempts to take sweeping action to restrict the use of a chemical.[69] Ultimately, the lack of a clear definition of "unreasonable risk," combined with the varying interpretations of the term, has limited the Agency's ability to

62. U.S. EPA, Revitalization of the Toxics Program (It's Not Just TSCA Anymore) (July 8, 1992) (unpublished document on file with author).
63. U.S. EPA, Enhancing Existing Chemical Management Under TSCA, http://www.epa.gov/opptintr/existingchemicals/pubs/enhanchems.html (last visited Mar. 18, 2011).
64. *Implementation of the Toxic Substances Control Act Hearing Before the Subcomm. on Toxic Substances, Environmental Oversight, Research, and Development of the S. Comm. on Environment and Public Works*, 102d Cong. 20 (1992) (statement of Linda J. Fisher, Assistant Administrator, Prevention, Pesticides, and Toxics, U.S. EPA).
65. CEQ, The President's 1971 Environmental Program 11 (1971).
66. U.S. EPA, Assessment and Control of Chemical Problems: An Approach to Implementing the Toxic Substances Control Act (Feb. 17, 1977) (unpublished document, on file with author).
67. J. Clarence Davies et al., Determining Unreasonable Risk Under the Toxic Substances Control Act 2 (1979).
68. *See* Ausimont USA Inc. v. EPA, 838 F.2d 93, 18 ELR 20456 (3d Cir. 1988) (stating that testing can be required by EPA "when an existing possibility of harm raises reasonable and legitimate cause for concern") and Chemical Manufacturers Assoc. v. EPA, 859 F.2d 977, 19 ELR 20001 (DC Cir. 1988) (stating that testing can be required "where there is a more-than-theoretical basis for suspecting that some amount of exposure takes place and that the substance is sufficiently toxic at that level of exposure to present an 'unreasonable risk of injury to health.'").
69. *See* Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 22 ELR 20037 (5th Cir. 1991) (requiring a rigorous cost-benefit analysis to justify an "unreasonable risk" determination).

Example: Influence of statutory mandates on the early implementation of TSCA's existing and new chemicals programs

The new chemicals program is considered to be one of the modest successes of TSCA, while the existing chemicals program is regarded as having very limited results. The drastically different outcomes of these programs demonstrate the role that mandates and clear deadlines play in implementation success.

The new chemicals program had specific mandates and deadlines detailed in the statute. As Linda Fisher highlighted, "the new chemical program was aided by clearer direction and deadlines in the statute. The Congress was rather precise when it directed the Agency . . . how to implement that program and put us on a time frame."[1]

On the contrary, the existing chemicals program was plagued by significant flexibility with no guidance on how to set priorities, no time frames for taking appropriate action on problematic chemicals, and no deadlines for completing regulatory action.[2] Steve Jellinek, the first Assistant Administrator for Pesticides and Toxics Substances in charge of TSCA implementation, described the difficulty that EPA faced with regards to prioritizing chemicals of concern during the outset of TSCA implementation: "one of the biggest problems with TSCA was that . . . there were no priorities set by the Congress for what's a chemical of concern. You're just faced with these massive numbers of chemicals, most of which are not of concern. . . . And at the same time, they throw in these hurdles—these procedural and legal hurdles—that make it difficult for the agency to come up with its own standards."[3] Then-Assistant Administrator of the Pesticides and Toxic Substances Office, Don Clay, echoed this sentiment in 1983, "one of the major problems with the existing chemicals program in the early years of TSCA was the absence of a coordinated process for identifying and characterizing potential risks, selecting those that warranted control [by the Office of Toxic Substances], and bringing specific issues to resolution."[4] This is further demonstrated by EPA's myriad approaches to prioritization, as detailed in the previous section, that were anything but consistent. Struggles over how to prioritize chemicals consumed significant time and resources dedicated to existing chemicals.

Where difficult choices about allocating limited resources arose, programs with statutory mandates, like the efforts on new chemicals, were favored at the expense of programs with less direction, guidance, and mandates, like the existing chemicals program.[5] As Jellinek explained, "the agency as a whole is putting a lot of time and effort . . . on existing chemicals than we could ever hope to put, with our limited resources on new chemicals. That is why we in the Office of Toxic Substances believe that in order to get the mileage we think we have to get out of TSCA, and in order to get the benefit that we can get out of using TSCA as a regulatory tool, we should concentrate our emphasis on the unique provisions that TSCA gave to the EPA and the country; one of these is the review of new chemicals. . . ."[6]

1. *Implementation of the Toxic Substances Control Act Hearing Before the Subcomm. on Toxic Substances, Environmental Oversight, Research, and Development of the S. Comm. on Environment and Public Works*, 102d Cong. 20 (1992) (statement of Linda J. Fisher, Assistant Administrator, Prevention, Pesticides, and Toxics, U.S. EPA).
2. U.S. GAO, TOXIC SUBSTANCES—EFFECTIVENESS OF UNREASONABLE RISK STANDARDS UNCLEAR (1990) (GAO/RCED-90-189), *available at* http://archive.gao.gov/d23t8/141845.pdf.
3. Interview by Jody A. Roberts & Kavita D. Hardy, with Steven D. Jellinek, Former Assistant Administrator for Pesticides and Toxic Substances, U.S. EPA, in Philadelphia, Pa. (Jan. 29, 2010).
4. *Toxic Substances Control Act Oversight Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the S. Comm. on Environment and Public Works*, 98th Cong. 117 (1983) (statement of Donald R. Clay, Acting Assistant Administrator, Pesticides and Toxic Substances Office, U.S. EPA).
5. See *Toxic Substances Control Act Oversight Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the S. Comm. on Environment and Public Works*, 98th Cong. 23, 117 (1983) (statement of Donald R. Clay, Acting Assistant Administrator, Pesticides and Toxic Substances Office, U.S. EPA).
6. *Authorizations and Oversight of the Toxic Substances Control Act Hearing Before the Subcomm. on Consumer Protection and Finance of the H. Comm. on Interstate and Foreign Commerce*, 96th Cong. 213 (1979) (statement of Steven D. Jellinek, Assistant Administrator, Toxic Substances, U.S. EPA).

effectively use its authorities, due to uncertainty as to the evidentiary burdens that must be met to take action.

B. Procedural Framework

The impact of procedural requirements on TSCA's implementation was best summed up in a 1994 congressional hearing:

> TSCA has, in some ways, been a statute with a good deal of authority, with some inherent contradictions that obscure its mission. It gives the EPA the authority to require chemical testing but provides cumbersome processes. . . . TSCA gives the EPA a broad range of options to control chemical risks through actions ranging from labeling to bans, but again, the process is extremely cumbersome. It gives the EPA extensive authority to collect health and safety information, but it greatly inhibits the dissemination of that information by allowing broad confidentiality claims. TSCA appears to need a clearer sense of its mission and more streamline processes.[70]

Over the years, EPA officials recognized the barriers that procedure played in implementing TSCA. Linda Fisher questioned whether "TSCA was drafted by people that had worked in or managed a bureaucracy. . . ." She noted that "conceptually a lot of it made sense, but the process they built in to accomplish things under TSCA . . . contributed

70. *Reauthorization of the Toxic Substances Control Act Hearing Before the Subcomm. on Toxic Substances, Research, and Development of the S. Comm. on Environment and Public Works*, 103d Cong. 2 (1994) (statement of Sen. Harry Reid).

to some of the problems the Agency has had."[71] Specifically, the rulemaking process, judicial review, burdens of proof, and CBI all shaped the ways in which EPA was able to use its authorities under TSCA.

1. Rulemaking

Rulemaking is central to the ability of EPA to require testing, collect information, or impose regulations on chemicals. The rulemaking process is inherently slow, as well as time- and resource-intensive.[72] It places a burden on the Agency to develop extensive findings and orchestrate elaborate comment and hearing processes. Even where rulemaking proceeds smoothly, the process unfolds over years. The efficiency of the rulemaking process is also directly tied to Agency resources. For example, promulgating a §4 test rule can take as long as 24 to 30 months, and costs have ranged between $68,500-$234,000.[73] As noted by an EPA official during a 1990 hearing, "in terms of the rulemaking process, the time between proposed and final is more a matter of resources and how many people we have on hand to devote to reviewing the public comments."[74] Thus, there is an opportunity cost in undertaking rules, in that resources could be applied to other efforts.

These procedural requirements, and associated resource requirements, directly contributed to the inability of EPA to require testing under §4 or collect information under §8. EPA struggled to issue chemical testing rules due in large part to the fact that testing had to be done through a rulemaking process, largely on a chemical-by-chemical basis (though §26 of TSCA allows for EPA to identify "chemical categories").[75] As one EPA official described it, the process "generally requires a minimum of about two years to identify the testing needs, go through the proposal, take public comment, and get a rule finalized."[76] EPA tried to act creatively about writing rules in order to make the process more efficient. For example, EPA attempted to establish model rules for the collection of manufacturing and use information that could then be applied to individual chemicals or groups of chemicals, instead of writing an individual rule for each chemical or group of chemicals. These model rules included PAIR and CAIR, as previously described. Although the development of model rules helped to streamline the rulemaking process and collect information more efficiently, EPA still faced many barriers to data collection. Ultimately, these procedural barriers moved EPA toward negotiated testing agreements with industry and other voluntary, rather than mandatory, efforts.

Example: The Procedural Problems of Data Collection

The ability of EPA to effectively collect chemical data was constrained by procedural requirements. This is illustrated by the different results EPA obtained when it attempted to collect data from industry by promulgating test rules (§4), by promulgating a model rule and specifying chemicals for which reporting was required (PAIR rule and IUR rule under §8(a)), and by having a self-implementing provision that required the submission of health and safety studies (§8(e) substantial risk reporting). To date, EPA has issued final test rules for 46 chemicals under §4, required use and exposure information reporting on 40 occasions covering 1,200 chemicals under the PAIR rule, required production and exposure information for 17,080 chemicals under the IUR rule,[1] and has received 17,985 initial §8(e) submissions. Thus, requiring the promulgation of rules as a prerequisite to data collection has presented a barrier to the effective collection of information under TSCA.[2]

1. E-mail from Darryl Ballard, Office of Chemical Safety and Pollution Prevention, U.S. EPA, to Jessica Schifano, Policy Analyst, Lowell Center for Sustainable Production (Mar. 25, 2011) (on file with author).
2. E-mail from Brian Symmes, Deputy Director of the National Program Chemical Division, Office of Chemical Safety and Pollution Prevention, U.S. EPA, to Jessica Schifano, Policy Analyst, Lowell Center for Sustainable Production (Dec. 14, 2010) (on file with author).

In the early stages of TSCA implementation, EPA officials were also concerned about the extent of their rulemaking authority. The legislative history of TSCA confirms that Congress intended to deny general substantive rulemaking authority to EPA, prohibiting the Agency from more formally issuing general standards and guidance through the rulemaking process, rather than case-by-case adjudications.[77] As Jellinek noted in 1978:

> general [substantive] rulemaking authority would assist in the implementation of the statute as a whole and specifically implementation of those sections of the statute which do not presently include specific rulemaking authority . . . substantive rulemaking . . . permits development of policy in a public forum, simplifies adjudication in individual

71. *Toxic Substances Control: Still Waiting After All These Years Hearing Before the Subcomm. on Environment, Energy, and Natural Resources of the H. Comm. on Government Operations*, 102d Cong. 83-4 (1992) (statement of Linda J. Fisher, Assistant Administrator, Prevention, Pesticides, and Toxic Substances, U.S. EPA).
72. Struggles with the federal rulemaking process are not limited to TSCA implementation or other implementation activities undertaken by EPA. Many critics have noted that procedures imposed by the courts, Congress, and the Executive Branch have "ossified" the federal rulemaking process over time. *See* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 Duke L.J. 1385 (1992).
73. U.S. GAO, Toxic Substances Control Act—Legislative Changes Could Make the Act More Effective (1994) (GAO/RCED-94-103), *available at* http://archive.gao.gov/t2pbat2/152799.pdf.
74. *The Failure of the Toxic Substances Testing Program Hearing Before the Subcomm. on Environment, Energy, and Natural Resources of the H. Comm. on Government Operations*, 101st Cong. 155 (1990) (statement of Linda J. Fisher, Assistant Administrator, Pesticides and Toxic Substances, U.S. EPA).
75. *See* NRDC v. Costle, 14 ERC 1858, 1980, 10 ELR 20274 (S.D.N.Y. 1980) (ordering EPA to develop procedures for responding within the mandated 12-month time limit for Interagency Testing Committee testing recommendations).
76. *Implementation of the Toxic Substances Control Act Hearing Before the Subcomm. on Toxic Substances, Environmental Oversight, Research and Development of the S. Comm. on Environment and Public Works*, 102d Cong. 19 (1992) (statement of Linda J. Fisher, Assistant Administrator, Prevention, Pesticides, and Toxics, U.S. EPA).
77. H.R. Rep. No. 94-1341 at 62, *reprinted in* House Comm. on Interstate and Foreign Commerce, 94th Cong., Legislative History of the Toxic Substances Control Act, at 407-16 (1976).

> cases, and prevents agency policy from being relitigated every time it is applied to a specific product. These economies can avoid substantial delays in the implementation of policy. . . ."[78]

Although EPA was granted general substantive rulemaking authority under other environmental laws, this authority was never extended to TSCA.

2. Burden of Proof

Placing the burden on EPA to demonstrate unreasonable risk before it could act, particularly under §6, proved to be a significant barrier to EPA's capacity to take timely and appropriate action on chemicals of concern. As the National Academy of Sciences (NAS) noted in a 1975 book, "because the scientific evidence regarding health and environmental effects is so difficult to obtain with precision, and because the costs of data collection can be so high, the party carrying the legal burden of proof is at a considerable disadvantage."[79] Although the congressional intent was for industry to provide data on chemicals, and early versions of TSCA placed the burden on the manufacturer to demonstrate the safety of the chemical,[80] the burden was ultimately allocated to EPA, thus placing EPA at the disadvantage suggested in the NAS report.

3. Judicial Review

In addition to strenuous rulemaking procedures and difficult burdens of proof, the majority of EPA's findings under TSCA must meet the higher judicial review standard of "substantial evidence" in order to withstand legal challenges to actions taken under the law, rather than the less demanding "arbitrary and capricious" standard applied to other similar rulemaking efforts.[81] This heightened standard for judicial review was included in the statutory language since the bill's introduction in 1971, due to early political compromises between the CEQ and representatives from the Department of Commerce.[82] As suggested by one critic, "substantial evidence is in fact a virtual invitation to the courts to substitute their judgment for EPA's."[83] While courts may interpret these judicial review standards differently, this high standard of review not only makes EPA's authority more arduous to implement, but it also provides a ready basis for challenging any TSCA rulemaking. In order to prevail on these challenges, EPA often spent excessive amounts of time and scarce resources preparing a record to withstand judicial review.

The effect of the substantial evidence standard on TSCA test rules is illustrated by a number of judicial decisions. Some test rule challenges resulted in remanding the rule to the Agency as a direct result of judicial review under this heightened standard.[84] Moreover, as one critic noted, the result of the substantial evidence standard adopted for judicial review of TSCA test rules is "that if industry merely raises doubts about several elements of the unreasonable risk standard . . . the courts must be receptive to the challenges."[85]

4. CBI

The ability for industry to assert CBI claims stalled not only EPA efforts to share information with other agencies and interested stakeholders, but also encumbered efforts to collect information from industry.

At the outset, EPA was burdened with the development and implementation of stringent security procedures to protect confidential business information from disclosure. In 1978, while undertaking efforts to compile the initial TSCA Inventory, EPA was sued by the Polaroid Corporation, who wanted guarantees of confidentiality before submitting information to EPA about the chemicals involved in its instant film developing processes.[86] As a result of the case, EPA agreed to upgrade its security of commercially valuable information by creating "a confidential business information document protection system that would approximate the military's classified document safeguards. EPA adopted a very significant process for the physical protection of documents with a security manual, locked rooms, controlled access, and passwords." Ultimately, "both EPA employee access and EPA contractor access to formula and process data was sharply curtailed."[87]

EPA did establish review processes to challenge confidential business information claims so that more information collected under TSCA could be released to the public. However, the processes quickly became unwieldy and resource-intensive. By 1983, Clay stated that

> we do not routinely challenge the confidential claims of the manufacturer who makes one. . . . We had a whole

78. *Toxic Substances Control Act Amendments Hearing Before the Subcomm. on Consumer Protection and Finance of the H. Comm. on Interstate and Foreign Commerce*, 95th Cong. 338-39 (1978) (statement of Steven D. Jellinek, Assistant Administrator, Toxic Substances, U.S. EPA).
79. NAS, Decision Making for Regulating Chemicals in the Environment 17 (1975).
80. *See* S. 1478, 92d Cong. (1971) (stating that "the manufacturer shall be responsible for supplying all information necessary to make findings" to restrict or prohibit the use of a chemical; *see also* House Comm. on Interstate and Foreign Commerce, 94th Cong., Legislative History of the Toxic Substances Control Act, at 257-59 (1976) (describing Amendment 21, which shifted the burden of proof to proponents of chemicals in certain circumstances).
81. Nicholas A. Ashford & Charles C. Caldart, Technology, Law, and the Working Environment 73-74 (1991).
82. Interview by Jody A. Roberts & Kavita D. Hardy with J. Clarence Davies, Former Senior Staff Member of the Council on Environmental Quality, in Washington, D.C. (Oct. 30, 2009).
83. John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 Colum. L. Rev. 261, 327 (1991).
84. *See* Chemical Mfrs. Ass'n v. EPA, 899 F.2d 344, 357-60, 20 ELR 20837 (5th Cir. 1990); *see also* Shell Chem. Co. v. EPA, 826 F.2d 295, 297-98, 17 ELR 21146 (5th Cir. 1987).
85. John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 Colum. L. Rev. 261, 326 (1991).
86. Polaroid Corp. v. Costle, 11 Env't Rep. Cas. (BNA) 2134 (D. Mass. June 23, 1978).
87. James T. O'Reilly, *Seeking a Truce in the Environmental Information Wars: Replacing Obsolete Secrecy Conflicts With New Forms of Sharing*, 30 ELR 10203, 10206 (Mar. 2000).

> procedure of going back and requesting more information. . . . Given the statutory definition of what was confidential, the General Counsel's Office at EPA was upholding the confidentiality claims. As a result, we don't routinely challenge CBI claims any more.[88]

A 1985 budget review hearing shed some light on the estimated resources necessary to comprehensively challenge all claims of confidentiality. EPA officials stated that 65 full-time equivalent personnel (FTEs) would be required to review and challenge all claims of confidentiality. However, at that time, only five FTEs were actually devoted to this activity.[89] However, efforts by EPA in the early 1990s suggested that fewer resources were actually needed to review and challenge all new CBI claims. During this time, EPA staff systematically and effectively reviewed and challenged new CBI claims with only three lawyers and a paralegal.[90]

In addition, concerns about CBI were routinely used by industry to stall EPA efforts to collect data. For example, the Society of Chemical Manufacturers and Affiliates (SOCMA) petitioned EPA and filed a Petition for Judicial Review in the U.S. Court of Appeals for the District of Columbia (D.C.) Circuit to stay the implementation of the final CAIR, due to concerns about the improper release of confidential business information and the requirements for substantiation of CBI claims at the time of submission. In response to this petition, EPA granted temporary administrative relief for certain reporting requirements that would result in the disclosure of a trade secret.[91] EPA attempted to amend the rule so it could begin to comprehensively collect manufacturing and use information; however, the amendments were never finalized, and EPA removed the regulation from the *Code of Federal Regulations* in 1995.[92] Overall, TSCA's history demonstrates that the Agency often spent significant amounts of time and resources reviewing and protecting confidential business information.

C. Political Context

Political factors, such as changing vision and leadership in the implementing agency, the absence of congressional champions and oversight, competing priorities in EPA, jurisdictional struggles, new regulatory challenges, and the presence and intensity of interest group involvement, all affected the implementation of TSCA.

1. Changing Vision and Leadership

Because Congress did not provide a clear mandate for TSCA in the statute, the task of defining the role and vision of TSCA was left to the Agency. In the early years of TSCA, EPA sought to define an approach to its implementation, which included the development of a broad vision and coherent agency-wide approach to toxic substances.[93] However, as implementation proceeded, the visions became increasingly narrow. In part, this was due to the conservative nature of EPA's Office of General Counsel. One EPA official involved in the early years of implementation described how he would argue with the lead EPA lawyer on TSCA with regards to the Agency taking bold actions:

> I would say, "you know, I don't care if we lose. Let's do something." Yet, he reported to the administrator through a separate [channel], so I couldn't tell him what to do. . . . To me that was . . . one of the things I remember most vividly about those three years was the frustration of getting the lawyers to [take risks that might result in losing cases].[94]

Moreover, many of these visions for approaching TSCA implementation changed completely when political changes occurred at the Agency. The most significant shift in direction occurred during the early 1980s, coinciding with a critical moment of implementation. In 1981, just as implementation was ramping up, the Republican party won the presidency, and regulatory efforts were largely put on the back burner in favor of voluntary approaches.[95] However, EPA had not yet had an opportunity to demonstrate its ability to regulate chemicals under TSCA. Thus, EPA's shift toward voluntary efforts was supported by a backstop of regulatory action only in theory, as EPA had never actually demonstrated that it could take action where there was a lack of cooperation and participation by industry in these voluntary efforts.

Other major shifts occurred in the early 1990s with the Fifth Circuit's *Corrosion Proof Fittings* decision[96] and the

88. *Toxic Substances Control Act Oversight Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the S. Comm. on Environment and Public Works,* 98th Cong. 24 (1983) (statement of Donald R. Clay, Acting Assistant Administrator, Pesticides and Toxic Substances Office, U.S. EPA).
89. *Fiscal Year 1986 Budget Review Hearing Before the S. Comm. on Environment and Public Works*, 99th Cong. 150 (1985) (statement of Lee M. Thomas, Administrator, U.S. EPA).
90. E-mail from Scott Sherlock, Attorney Advisor, Environmental Assistance Division, Office of Pollution Prevention and Toxics, U.S. EPA, to Jessica Schifano, Policy Analyst, Lowell Center for Sustainable Production (Mar. 21, 2011) (on file with author).
91. Comprehensive Assessment Information Rule—Notice of Temporary Administrative Relief, 54 Fed. Reg. 14324 (Apr. 10, 1989).
92. *See* Comprehensive Assessment Information Rule—Proposed Amendments, 58 Fed. Reg. 63134 (Nov. 30, 1993); *see also* Chemical Substances—Deletion of Certain Chemical Regulation, Technical Amendments to the Code of Federal Regulations, 60 Fed. Reg. 31917 (June 19, 1995).
93. Toxic Substances Control—Proposed Approach to Implementing the Toxic Substances Control Act, Request for Public Comment, 43 Fed. Reg. 50140 (Oct. 26, 1978).
94. Interview by Jody A. Roberts & Kavita D. Hardy with Steven D. Jellinek, Former Assistant Administrator for Pesticides and Toxic Substances, U.S. EPA, in Philadelphia, Pa. (Jan. 29, 2010).
95. *See Reauthorizations Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the S. Comm. on Environment and Public Works*, 97th Cong. 18 (1981) (statement of Edwin H. Clark II, Acting Assistant Administrator, Pesticides and Toxic Substances, U.S. EPA)*; see also Implementation of the Toxic Substances Control Act Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the S. Comm. on Environment and Public Works*, 97th Cong. 1-2 (1982).
96. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 22 ELR 20037 (5th Cir. 1991).

passage of the Pollution Prevention Act.[97] EPA's rebuke in the former, despite years of regulatory record, demoralized the Agency and led it to question the opportunity costs of using its §6 authorities. However, the PPA provided an opportunity for the Agency to use its discretionary powers to bring together chemical manufacturers, users, and other stakeholders and facilitate the introduction of safer chemicals, processes, and products to the marketplace. Although this voluntary focus shifted resources away from the direct implementation of EPA's regulatory authorities under TSCA, the new vision reinvigorated EPA's broader efforts on toxics and attempted to infuse the tools of TSCA with the mission of pollution prevention. As Linda Fisher described:

> one of the ways that we have thought about at the Agency is to look at the pollution prevention hierarchy that the Congress laid out in the Pollution Prevention Act which basically instructed the Agency to focus on source reduction as the preferred way of dealing with environmental hazards and maybe tying that into how we approach dealing with chemicals causing risks under TSCA.[98]

2. Absence of Congressional Champions and Oversight

After the passage of TSCA in 1976, the law largely became an "orphan statute" in Congress. Unlike other environmental statutes that went through the U.S. Senate Environment and Public Works Committee, TSCA was shepherded through the Senate Commerce Committee. However, in 1977, shortly after TSCA's passage, a major Senate reorganization changed the congressional jurisdiction of TSCA from the Commerce Committee to the Environment and Public Works Committee. As the Senate Environment and Public Works Committee had not been instrumental in the development and passage of TSCA, it did not treat TSCA in the same manner as other environmental statutes. As Jellinek explained:

> The Environment and Public Works Committee hated TSCA. They hated it when the Commerce Committee was first working on it. The staff of the Environment and Public Works Committee had enacted the Clean Air [Act], Clean Water [Act]. They were working on the things that would become eventually RCRA [Resource Conservation and Recovery Act], Superfund [Comprehensive Environmental Response, Compensation, and Liability Act], [and the Safe Drinking Water Act]. They were very strong environmental advocates. Senator [Edmund S.] Muskie was [chairman of the Senate Environment Committee and] Leon [G.] Billings was the staff director. They were tough, pro-environment liberals. The Commerce Committee in the Senate was not. It was a business-oriented committee. They produced TSCA. They—the Environment and Public Works Committee guys—were sniping at TSCA all during the period of its legislative enactment. Then they got [jurisdiction over] it. They, basically, proceeded to ignore it.[99]

In addition, leading advocates of TSCA in the Senate disappeared from Congress in succeeding election cycles. With the absence of leadership in Congress, there was a void of congressional action on TSCA that resulted in little oversight of the law as its implementation progressed.

3. Competing Priorities in EPA

During the late 1970s and early 1980s, EPA's responsibilities also expanded dramatically with the passage of new laws and the enactment of amendments to existing laws. As then-EPA Administrator, Douglas Costle, explained in 1978: "in the last 6 years, Congress has enacted 13 major pieces of legislation, each of which substantially expands EPA's responsibilities. . . . Almost as quickly as science has revealed a new danger to human health, Congress has asked EPA to deal with it."[100] The view of TSCA as only a "gap-filling" statute rather than a centerpiece of environmental regulation made it a lower priority for EPA overall. Ultimately, TSCA was seen as a "quiet environmental statute that doesn't generally receive the attention that other environmental issues do."[101]

4. Jurisdictional Struggles

The "gap-filling" nature of TSCA was reinforced by §9, which contains a requirement for EPA to refer regulatory responsibility under TSCA to other administrative agencies or branches of EPA if the regulations under the statutes that they administer can adequately reduce a chemical risk. Instead of preventing jurisdictional overlap, it became "an escape hatch for the EPA to avoid regulatory responsibility that it should legitimately exercise."[102]

During the mid-1980s, the scope of §9 referrals was significantly broadened by an EPA policy statement issued in 1985 by then-Acting General Counsel, Gerald Yamada. The policy issued specific referral guidelines for §9(a) and stated that EPA had the obligation to liberally use the section to refer regulatory responsibility. The policy promoted referral away from EPA whenever feasible and also stressed that EPA's disagreement with the regulatory

97. Pollution Prevention Act of 1990, 42 U.S.C. §§13101-13109 (2010).

98. *Implementation of the Toxic Substances Control Act Hearing Before the Subcomm. on Toxic Substances, Environmental Oversight, Research and Development of the S. Comm. on Environment and Public Works*, 102d Cong. 33 (1992) (statement of Linda J. Fisher, Assistant Administrator, Prevention, Pesticides, and Toxics, U.S. EPA).

99. Interview by Jody A. Roberts & Kavita D. Hardy with Steven D. Jellinek, Former Assistant Administrator for Pesticides and Toxic Substances, U.S. EPA, in Philadelphia, Pa. (Jan. 29, 2010).

100. *Fiscal Year 1979 Budget Review Hearing Before the S. Comm. on Environment and Public Works*, 95th Cong. 173-74 (1978) (statement of Douglas M. Costle, Administrator, U.S. EPA).

101. *Reauthorization of the Toxic Substances Control Act Hearing Before the Subcomm. on Toxic Substances, Research and Development of the S. Comm. on Environment and Public Works*, 103d Cong. 1 (1994) (statement of Sen. Harry Reid).

102. Cynthia Ruggiero, *Referral of Toxic Chemical Regulation Under the Toxic Substances Control Act: EPA's Administrative Dumping Ground*, 17 B.C. Envtl. Aff. L. Rev. 75, 77 (1989-1990).

approach of another agency was not a sufficient basis to withhold a referral.[103]

Moreover, where chemicals were referred to other agencies for action, EPA had little oversight with regard to how regulatory efforts proceeded and no input with regards to the actions that were or were not taken. As noted in a 1994 congressional oversight hearing, "with the current referral process under §9, it can take 7 to 10 years from the time EPA refers a chemical to OSHA to the time OSHA issues a formal rule."[104] In addition to a substantial time lag between referral and agency action, chemicals referred to other agencies were not given the same priority for regulation, and the action ultimately taken under different statutory authorities was often not as comprehensive as actions that might have been considered under TSCA. For example, in 1986, EPA informally referred 4,4'-methylene bis (2-chloroaniline), known as MOCA, to OSHA. Although MOCA is a carcinogen that presents threats to workers, its presence in the environment is also a concern. Despite this, EPA chose to defer to OSHA for its regulation, ignoring both concerns about the chemical in the environment and industry's call for a more comprehensive packaging and labeling regulation that could only be promulgated under TSCA. Ultimately, OSHA failed to take action on MOCA, and regulatory efforts on the chemical were discontinued.[105]

5. New Regulatory Challenges

Under the Clean Air Act (CAA)[106] and Clean Water Act (CWA),[107] EPA regulates pollution, which does not have a public benefit. Chemicals, on the other hand, serve important purposes in society that must be weighed against the risks of continued use. EPA had never undertaken this type of analysis to inform regulatory decisionmaking prior to TSCA. Jellinek described the complications with regulating products:

> Under TSCA, EPA must deal with products that someone in society believes have some utility, some intrinsic benefit themselves. While there may be some problems and some undesirable side effects with some of these substances, before the agency can take an action against a product, we ought to take a look at the benefits and crank those benefits into its decisionmaking process. I think that is basically a good idea when you are dealing with a product that to someone has social utility. Whether or not that proves to be overly restrictive in dealing with what we think are real problems and real risks, remains to be seen.[108]

Similarly, Congress had never created a standard to evaluate the balance of costs and benefits prior to TSCA.

This new method for analysis proved to be a substantial hardship, especially for the regulation of existing chemicals. Since existing chemicals often had substantial investments and business built on them, the balance of costs and benefits was very different from that of new chemicals. Chemicals already on the market were construed from the outset as beneficial to society, in part leading to the small number of existing chemicals regulated. Neither Congress nor EPA was able to strike the appropriate balance for regulating products during the early years of TSCA implementation.

6. Presence and Intensity of Interest Group Involvement

After the passage of TSCA, participation by many stakeholder groups waned, particularly environmental advocates and labor, while efforts by industry flourished. A book compiled by the Chemical Manufacturers Association (CMA), entitled *The First Four Years of the Toxic Substances Control Act*, details the intense industry involvement in TSCA implementation.[109] It states:

> since the enactment of TSCA, CMA has regarded EPA's implementation of this new statute as a matter of highest interest to CMA members. In late 1976, CMA formed the Chemical Regulations Advisory Committee (CRAC) to coordinate CMA's interests in TSCA. Appropriate CRAC Task Forces were organized to monitor EPA activities, discuss matters with the Agency, formulate and recommend policy positions to CMA's Board of Directors, participate at EPA public meetings, and develop written comments on specific proposals.[110]

Through these well-coordinated efforts, CMA was able to submit "extensive written comments to EPA on virtually every one of [the] proposed regulations."[111] Thus, industry was able to exert substantial influence on the outcome of EPA rulemaking and thus delay any attempts for EPA to take action.

As Edward J. Woodhouse described in his evaluation of TSCA implementation, "weak outside scrutiny insulate[d] the regulatory system from substantive criticism that could [have led] to improved effectiveness." For example, with regards to priority-setting for testing:

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103. Memorandum from Gerald H. Yamada, U.S. EPA Acting General Counsel, to Lee M. Thomas, U.S. EPA Acting Administrator, The Relationship of the Toxic Substances Control Act to Other Federal Programs Under Section 9 (Jan. 31, 1985).
104. *Reauthorization of the Toxic Substances Control Act Hearing Before the Subcomm. on Toxic Substances, Research and Development of the S. Comm. on Environment and Public Works*, 103d Cong. 100 (1994) (statement of Sen. Harry Reid).
105. *See* Cynthia Ruggiero, *Referral of Toxic Chemical Regulation Under the Toxic Substances Control Act: EPA's Administrative Dumping Ground*, 17 B.C. Envtl. Aff. L. Rev. 75, 103-04 (1989-1990); *see also* 4,4-Methylene Bis (2-Chloroaniline)—Termination of Regulatory Investigation and Transfer of Information to the Occupational Safety and Health Administration, 51 Fed. Reg. 22836 (June 23, 1986).
106. 42 U.S.C. §§7401-7671q, ELR Stat. CAA §§101-618.
107. 33 U.S.C. §§1251-1387, ELR Stat. FWPCA §§101-607.
108. *Toxic Substances Control Act Oversight Hearing Before the Subcomm. on Environmental Pollution of the S. Comm. on Environment and Public Works*, 95th Cong. 29 (1978) (statement of Steven D. Jellinek, Administrator, Toxic Substances, U.S. EPA).
109. CMA, The First Four Years of the Toxic Substances Control Act: A Review of Environmental Protection Agency's Progress in Implementing TSCA (1981).
110. *Id.* at iii.
111. *Id.* at ii.

> EPA has organized scoping workshops since 1981 to "request industry, environmental groups, labor, academic experts, and the general public to help EPA staff identify and discuss issues regarding how the Agency should respond to recommendations." According to the EPA official in charge, "I've tried pretty hard to get the AFL-CIO and the Oil and Chemical Workers Union involved. It's really unfortunate, but they have too few people to handle it." Nor do environmental or outside medical-scientific representatives attend. The long-term effectiveness of the program has to be questioned when there is such a weak countervailing force against the pressure that industry inevitability will bring in support of its perceived interests.[112]

Charles Elkins also experienced the environmental community's waning interest in their efforts during his tenure as the Director of the Office of Toxic Substances in the late 1980s. He noted:

> in the first years of the agency, there was a very strong constituency for the agency. . . . When Ronald Reagan came [into the] presidency, the whole world changed. The environmental groups decided that there was no receptive ear at the agency. . . . So they abandoned their lobbying efforts to a large degree.

This resulted in what Elkins described as a "'two-way conversation.' It was between [EPA] and industry, and there was nobody [else]. There was no environmental group [that we could find to come in and sit] there pounding on the table."[113]

At the outset of implementation, the CMA identified a number of principal concerns with EPA's implementation and mounted aggressive efforts to redirect EPA's actions on chemical data collection and CBI protections. Among other suggestions, CMA stated: "EPA should seek information only when it is needed to further specific and defined regulatory objectives and should not demand the collection and submission of large amounts of information for its own sake" and "EPA must make a greater effort to recognize the legal and commercial necessity of protecting confidential business information."[114]

Industry advocacy for these positions did make a difference with regards to EPA's approach to data collection and confidential business information. For example, EPA initially tried to establish recommended testing guidelines for all new chemicals. However, Jellinek stated in a 1978 speech that

> for many chemicals, we know that it would not be commercially feasible to perform even moderate levels of health and environmental effects testing. . . . This issue exposes a basic tension in TSCA's approach to premanufacture notification. Surely Congress intended EPA to be able to make informed decisions on new chemicals. Yet Congress also wanted to protect the industry's innovative capacity.[115]

Therefore, the Agency did not establish testing rules for new chemicals.

With regards to confidential business information in the PMN review process, EPA attempted to require up-front substantiation of confidentiality claims. This requirement was included in EPA's interim policy statement on PMN submissions in 1980, but was changed in the Final PMN Rule to require substantiation only after receiving a request under FOIA.[116] EPA noted that "by not requiring 'up-front' substantiation of all claims, submitters will not have to incur the burden of substantiation unnecessarily."[117] Ultimately, this policy change resulted in a significant increase in the proportion of PMN submissions presenting CBI claims.[118]

D. Resources

Throughout much of TSCA's history, both financial and human resources were lacking, especially at critical points during the implementation of the law. At the outset, the appropriations for TSCA implementation constituted a relatively modest financial base compared to other environmental laws.[119] Even where Congress was supportive of increased funding to support these activities, the Agency struggled to identify appropriate budget requests for TSCA implementation. The late 1970s were marked by large requests that were eventually scaled back, due to concerns about EPA's ability to make the program grow efficiently.[120] When questioned by Congress about the large cutbacks in budget requests, Douglas Costle responded that "we need to walk before we run, and quite candidly, Mr. Chairman, it is a judgment call, and it is an estimate of the pace at which we are going to be able to effectively do this."[121]

At that time, EPA was contemplating the integration of toxics work throughout the Agency, and as a result, EPA advocated for a single-budget item for all toxics work at the Agency, rather than a separate pool of resources for TSCA implementation. This single-budget item encompassed

112. Edward J. Woodhouse, *External Influences on Productivity: EPA's Implementation of TSCA*, 4 Pol'y Stud. Rev. 497, 501 (1985).
113. Interview by Jody A. Roberts & Kavita D. Hardy with Charles L. Elkins, Former Director of the Office of Toxic Substances, U.S. EPA, in Washington, D.C. (Apr. 9, 2010).
114. CMA, The First Four Years of the Toxic Substances Control Act, *supra* note 109, at 7-9.
115. Steven D. Jellinek, Assistant Administrator for Toxic Substances, U.S. EPA, Remarks Before the Midland Section of the American Chemical Society, TSCA Two Years After: Taking Stock (Nov. 4, 1978).
116. Premanufacture Notification—Premanufacture Notice Requirements and Review Procedures, 48 Fed. Reg. 21722 (May 13, 1983).
117. *Id.*
118. Sheila A. Ferguson et al., Influence of CBI Requirements on TSCA Implementation (1992).
119. *Authorization of the Toxic Substances Control Act Hearing Before the Subcomm. on Commerce, Transportation, and Tourism of the H. Comm. on Energy and Commerce*, 97th Cong. 2 (1981) (statement of Representative Lent).
120. *Fiscal Year 1980 Budget Review Hearing Before the S. Comm. on Environment and Public Works*, 96th Cong. 1217 (1979).
121. *Toxic Substances: Amendments to Toxic Substances Control Act (Part 3) Hearing Before the Subcomm. on Science, Technology, and Space of the S. Comm. on Commerce, Science, and Transportation*, 95th Cong. 1809 (1977) (statement of Douglas M. Costle, Administrator, U.S. EPA).

funding for efforts across programs, including efforts under the CWA and the CAA. Thus, resources for toxics work could easily be diverted to fund more well-established regulatory efforts under other laws, rather than applying the resources to establish fully-functioning chemicals programs under TSCA.[122]

Despite these early struggles, the budget for TSCA implementation increased steadily during the late 1970s. However, the budget for EPA as a whole then decreased throughout much of the 1980s. As budgets tightened for EPA overall, the cuts significantly affected the resources available for TSCA implementation. The 1982 budget for TSCA implementation was reduced compared to previous years, the 1983 budget represented a decrease of nearly $27 million for work on TSCA implementation, and the 1984 budget included a further decline from 1983 funding levels. Overall, from 1981-1986, the budget for toxics programs at EPA was cut by 27%,[123] "reflect[ing] a shift in emphasis from a rigid regulatory approach for controlling chemicals toward initiating more voluntary efforts."[124] By 1986, the overall EPA budget was making a recovery, but the upswing only restored the budget to 1979 levels and did not reestablish previous levels of financial support.[125] Unfortunately, these budget cuts coincided with a critical period of implementation ramp-up and contributed to the inability to implement the law.[126]

By the late 1980s and early 1990s, the resource levels remained constant, but EPA's responsibilities with regards to toxics had significantly expanded to include new programs (such as a program on lead, voluntary programs such as the 33/50 Program, and pollution prevention, as well as the expanded implementation of the Toxics Release Inventory). These new responsibilities, taken with constant resource levels, resulted in a significant decrease in the levels of funding for core TSCA implementation activities, including efforts on new chemicals, existing chemicals, testing, asbestos, and PCBs.[127]

Over the last decade, the resource allocation to "core TSCA" programs has remained stagnant. In 1999, the TSCA program operated on a budget of approximately $30 million, supported by a staff of approximately 270 people. In 2008, the TSCA program operated on a budget of approximately $50 million, with the staffing levels unchanged since 1999.[128]

As a result of these budget constraints, EPA was often forced to make difficult decisions about allocating limited resources. The bulk of the resources were invested in TSCA programs where clear direction and statutory mandates and deadlines existed. Resources were also directed to efforts that were not already being addressed by other existing EPA programs, such as new chemicals and then later to specific voluntary programs. Thus, in times of scarce resources, EPA made decisions to cut programs without statutory deadlines or with existing efforts in other EPA programs.[129] It was not until 1985 that EPA began to consider a shift of resources from deadline-driven review of new chemicals and toward review of the hazards associated with existing chemicals.[130]

In addition to financial resources, human resources for TSCA were also limited. There was some difficulty in recruiting trained experts in the emerging fields of toxicology, pharmacology, and epidemiology during the early years of TSCA.[131] A hiring freeze from the onset of TSCA implementation until fiscal year (FY) 1980 presented another unanticipated barrier to initial efforts to staff the program.[132]

Over time and as a result of budget reductions during the 1980s, the Office of Toxic Substances staff dwindled. As Clay testified in 1983: "there are 100 some less people in the Office of Toxic Substances than when I came in the door 2 years ago."[133] In addition, a Congressional Budget Office analysis documented a 15% reduction in full-time employment in the toxics program from 1981-1984.[134]

The lack of adequate and consistent financial and human resources played a key role in the implementation of TSCA. As the budget of the entire EPA was significantly reduced during times of increasing responsibilities for the Agency, TSCA's "gap-filler" status made it a low priority for funding. Unfortunately, the scarce budgets aligned with critical periods of TSCA implementation. Although this affected all aspects of TSCA implementation, it ultimately played the most significant role in the

122. *Toxic Substances: Amendments to Toxic Substances Control Act (Part 3) Hearing Before the Subcomm. on Science, Technology, and Space of the S. Comm. on Commerce, Science, and Transportation*, 95th Cong. 1811 (1977) (statement of Douglas M. Costle, Administrator, U.S. EPA).

123. *Fiscal Year 1986 Budget Review Hearing Before the S. Comm. on Environment and Public Works*, 99th Cong. 5 (1985).

124. Congressional Budget Office, The Environmental Protection Agency: Overview of the Proposed 1984 Budget 39 (Apr. 1983), *available at* https://www.cbo.gov/ftpdocs/50xx/doc5066/doc17a.pdf.

125. *Fiscal Year 1986 Budget Review Hearing Before the S. Comm. on Environment and Public Works*, 99th Cong. 5 (1985).

126. *Id.* at 171.

127. *Toxic Substances Control: Still Waiting After All These Years Hearing Before the Subcomm. on Environment, Energy, and Natural Resources of the H. Comm. on Government Operations*, 102d Cong. 36-37 (1992) (statement of Linda J. Fisher, Assistant Administrator, Prevention, Pesticides, and Toxic Substances, U.S. EPA).

128. Mark A. Greenwood, *TSCA Reform: Building a Program That Can Work*, 39 ELR 10034 (Jan. 2009).

129. *Toxic Substances Control Act Oversight Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the S. Comm. on Environment and Public Works*, 98th Cong. 23 (1983) (statement of Donald R. Clay, Acting Assistant Administrator, Pesticides and Toxic Substances Office, U.S. EPA).

130. *Fiscal Year 1986 Budget Review Hearing Before the S. Comm. on Environment and Public Works*, 99th Cong. 129 (1985).

131. *Nomination of Steven D. Jellinek Joint Hearing Before S. Comm. on Environment and Public Works and S. Comm. on Commerce, Science, and Transportation*, 95th Cong. 12 (1977).

132. *Fiscal Year 1980 Budget Review Hearing Before the S. Comm. on Environment and Public Works*, 96th Cong. 1218 (1979).

133. *Toxic Substances Control Act Oversight Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the S. Comm. on Environment and Public Works,* 98th Cong. 23 (1983) (statement of Donald R. Clay, Acting Assistant Administrator, Pesticides and Toxic Substances Office, U.S. EPA).

134. Congressional Budget Office, The Environmental Protection Agency: Overview of the Proposed 1984 Budget 39-40 (Apr. 1983), *available at* https://www.cbo.gov/ftpdocs/50xx/doc5066/doc17a.pdf.

marginalization of the existing chemicals program during the early years of implementation.

V. Conclusion: The Influence of Statutory, Procedural, Political, and Resource Factors on Actions to Address Key Chemicals Management Challenges

As detailed above, the evolution of TSCA can best be explained by the convergence of the statutory, procedural, political, and resource factors that shaped its implementation. The ambitious statutory language was restrained by the procedural requirements, while the political context subverted the mission and limited the resources. This is illustrated by the ways in which EPA attempted to, but ultimately never fully resolved, key chemicals management challenges through TSCA's implementation, including prioritizing chemicals of concern, establishing a minimum chemical data set for new and existing chemicals, taking appropriate and timely action on chemicals, and providing access to chemical information.

The lack of statutory mandates, coupled with the inability of EPA to set standards defining priority chemicals due to procedural and legal hurdles and the lack of investment in the existing chemicals program made prioritizing chemicals of concern a difficult, if not impossible, task for EPA. As a result, EPA made the task of identifying priority candidates from the large number of existing chemicals a never-ending endeavor. Relying on a variety of prioritization methods over time, this inconsistency hampered further work on existing chemicals.

Although EPA made multiple attempts to establish minimum chemical data requirements for both new and existing chemicals, these efforts fell short. EPA did not begin with a big vision for collecting data, due to the Agency's limited resources, internal resistance from the Office of General Counsel, and strong industry opposition. The fact that most data collection, especially with regards to existing chemicals, required chemical-by-chemical rulemaking also played a substantial role, as this took a long time and required a significant investment of resources. Additionally, industry used concerns about the release of confidential business information to push back on Agency efforts to collect information.

The struggle to balance the dual mandates to provide public access to information and protect legitimate trade secrets and confidential business information was never adequately resolved. Like efforts to develop minimum chemical data, efforts to develop effective CBI policies were hampered by the lack of a big vision. There was a continual debate about what information should legitimately be CBI and what information should never be claimed as CBI. Although EPA began its TSCA implementation with strong up-front substantiation requirements and challenge programs, many of these efforts were diluted over time.

Although the "unreasonable risk" standard is cited as the key barrier to taking appropriate and timely action on chemicals, EPA's ability to do so was also hampered by the lack of a clear mandate and timetables, the new challenges faced by regulating products that were of beneficial use, and procedural barriers, including the judicial review standard, the burdensome rulemaking processes, and EPA's burden in demonstrating chemical risk. The high procedural burden on the Agency, combined with an uncertainty as to whether any particular regulatory effort would withstand legal challenge, led the Agency to question the opportunity costs of investing in regulatory activities. In addition, the Agency's shift in focus from regulation to voluntary efforts diminished the resources needed for regulatory actions on problematic chemicals.

Ultimately, the interplay of statutory, procedural, political, and resource factors resulted in EPA's inability to fully implement TSCA's ambitious regulatory agenda. In the future, as Congress contemplates changing or amending TSCA, it is important to be respectful of the many interacting factors that have beset implementation of the law. Statutory language is surely important, but procedural, political, and resource factors are also crucial to future success. A failure to consider implementation from the earliest stages of policy development will inevitably result in missed opportunities, wasted resources, and reduced impacts of our federal chemicals policies in protecting health and the environment.