Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

The Price of Chemical Control: Learning From Struggle and Success

by Charles L. Franklin

Charles L. Franklin is Senior Counsel at Akin Gump Strauss Hauer & Feld LLP. Before entering private practice, he spent 13 years at the U.S. Environmental Protection Agency, including 11 years in what is now the Office of Chemical Safety and Pollution Prevention. The author thanks Martha Marrapese for her helpful insights with the manuscript.

When President Gerald Ford signed the Toxic Substances Control Act (TSCA)[1] into law in 1976, he declared it "one of the most important pieces of environmental legislation . . . enacted by the Congress," one that would "close a gap in our current array of laws to protect the health of our people and the environment."[2] History has not been kind to President Ford's prediction. Throughout its 37-year implementation period, commentators have cited TSCA more for its shortcomings than for its accomplishments, and the public literature is replete with papers, arguments, and opinions on the need to reform, modernize, or revolutionize federal chemical control policy.

To be sure, TSCA's language and construction raise legitimate challenges for regulators seeking to take quick and decisive action in the face of limited information. Stakeholders rightfully have cited the statute's "least burdensome" risk-management requirement, the "substantial evidence" judicial review standard, and the need to consider cost and benefits of action as complicating factors in federal action. Still, similar requirements have existed in other statutes without the paralyzing effect on regulatory action. Why were the same provisions so problematic in this case?

There is no single answer, of course, but, one aspect of the chemical control policy process has received lip service, but little detailed analysis: The importance of adequate and consistent funding from a predictable source.[3] This Article looks at two other federal product regulatory systems, federal drug safety regulation and federal pesticide safety regulation, for insight as to the magnitude of resources required to operate first-class product regulatory programs, generally, and the importance of stable funding mechanisms in particular. Even a brief comparison of TSCA's budgetary history against these other statutes reinforces one important moral: You get what you pay for.

I. The Birth of TSCA

In 1971, the president's Council on Environmental Quality (CEQ) issued its Report on Toxic Substances citing the "high-priority need for a program of testing and control of toxic substances." The report recognized:

> Most toxic substances are not exclusively air or water pollutants but can be found in varying quantities in air, water, soil, food, and industrial and consumer products. The multiplicity of ways by which man can be exposed to these substances makes it difficult for the media-oriented authorities to consider the total exposure of an individual to a given substance, a consideration necessary for establishment of adequate environmental standards.[4]

Despite the compelling nature of the 1971 report and concerted Administration efforts to move a CEQ-authored chemical control bill through the legislative process, it took until October 1976 for the U.S. Congress to pass and the president to sign the final TSCA. The ultimate catalyst for federal action was a familiar combination: increased public awareness of a potential public safety concern (new reports on the danger of polychlorinated biphenyls (PCBs), mercury, and other toxic substances and their presence in the environment), highlighted by a high-profile environmental incident—the 1975 chemical facility disaster in Hopewell, Virginia, which poisoned workers and caused significant contamination to the adjacent James River).[5]

1. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.
2. Gerald Ford, *Statement on Signing the Toxic Substances Control Act* (Oct. 12, 1976), *available at* http://www.presidency.ucsb.edu/ws/?pid=6445.
3. Several notable exceptions include the 2009 ELR article by Mark Greenwood, *The Importance of Implementation in Rethinking Chemicals Management Policies: The Toxic Substances Control Act*, 39 ELR 10035 (Jan. 2009), and the 2011 ELR article by Jessica Schifano et al. on *The Importance of Implementation in Rethinking Chemicals Management: The Toxic Substance Control Act*, 41 ELR 10527 (June 2011) (2011 ELR TSCA Implementation Paper). This paper builds on points raised in these articles with respect to budgetary implementation of TSCA.
4. CEQ, *Toxic Substances*, Misc. Agency Reports 1971; TSCA Leg. Hist. 47 (1971).
5. *See, e.g.*, Report of the Senate Committee on Commerce on S. 3149, 94 Cong. Senate Report 698 [hereinafter Senate Report]; TSCA Leg. Hist. 14, *4 (Mar. 16, 1976); *see also* U.S. EPA, *The Toxic Substances Control Act: History and Implementation* (EPA TSCA History), *available at* http://www.epa.gov/oppt/newchems/pubs/chem-pmn/appendix.pdf.

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

TSCA built on an existing framework of environmental statutes regulating industrial, commercial, and agricultural releases of chemical pollutants to air, water, and land. Unlike these media-specific statutes, however, TSCA authorized the U.S. Environmental Protection Agency (EPA) to manage chemical substances *before* they reached the stack, pipe, or landfill. EPA could require manufacturers and processors to generate and provide data on the health and environmental hazards of a substance, and the risks associated with exposure.[6] EPA would receive premanufacture notice before companies introduced new substances to the U.S. market or engaged in significant new uses of existing substances, giving EPA the opportunity to take action where substances or uses might present an unreasonable risk to human health or the environment. For the thousands of chemicals already in commerce at the time of TSCA's passage, the statute outlined a variety of options available to EPA in managing unreasonable risks, from mandatory labeling and caution statements to use restrictions to chemical bans.

Unfortunately, TSCA's open-ended mandate, broad scope and reach, and unusual legislative history also created challenges for EPA's chemical control program. The laws governing air and water pollution had been developed or vetted through the U.S. House of Representatives Energy and Commerce Committee and the U.S. Senate Environment and Public Works Committee, both experienced with environmental legislation. In contrast, TSCA was developed through the House and Senate Commerce Committees, both more comfortable with promoting interstate and international commerce than environmental regulation.[7]

As a result, while the final statute gave EPA a broad range of regulatory tools to use in managing chemical risks, it also contained a variety of substantive and procedural checks and balances that increased the time, cost, and uncertainty of government action. EPA could require testing, but only after justifying the need for the data through a lengthy rulemaking process.[8] EPA could impose regulatory restrictions on new substances, significant new uses, and existing chemicals, but only after finding that the substance or use posed an "unreasonable risk of injury to human health and the environment."[9] If EPA acted to mitigate risk from a substance already in commerce, it had to select the "least burdensome risk mitigation option" and to consider the net benefits of the substance and the availability of alternatives.[10] Moreover, on judicial review, EPA faced the heightened "substantial evidence" review standard reserved for on-the-record proceedings, rather than the more deferential "arbitrary and capricious" standard used in most environmental rulemakings.[11]

There is little doubt that such procedural quirks increased the burden of government action under TSCA, and contributed to EPA's difficulty in using its risk assessment and risk-management authority. Still, it is unfair to suggest that TSCA was doomed to fail based on the legislative language alone. Many of the legislative provisions commonly cited for TSCA's downfall have been used, and remain in use, without such crippling impacts in other regulatory frameworks. The "least burdensome" risk-management requirement is also present in the 1972 Consumer Product Safety Act (CPSA).[12] Both the CPSA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[13] adopt safety standards based on principles of "unreasonable risk,"[14] and both statutes, like the Federal Food Drug and Cosmetic Act (FFDCA), use the "substantial evidence" standard in reviewing federal risk-management decisions.[15] While every statute is subject to criticism, these statutes are hardly considered failures.

Why, then, have these procedures and legal phrases created so much trouble in the TSCA context? The answer requires a look beyond the "letter of the law" to the numbers. These numbers explain how a law originally intended to fill "gaps" in the federal regulatory framework revealed both the significance of chemicals to the U.S. economy and the enormity of the task facing regulators in implementing a comprehensive chemical control program. The numbers also document the TSCA program's chronic underfunding and staffing, particularly when compared against other product regulatory programs of smaller magnitude and scope. Together, the numbers demonstrate how, without adequate resources, the best-intentioned legal mandates will come up wanting.

II. TSCA's Penurious History

Upon TSCA's enactment, EPA assumed responsibility for the largest and most diverse class of substances and prod-

6. *See generally* 15 U.S.C. §§2601-2629.
7. *See, e.g.*, House Interstate and Foreign Commerce Committee Report 94-1341, Reporting H.R. 14032 (July 14, 1976) [hereinafter House Report]; Senate Report, *supra* note 5.
8. 15 U.S.C. §2603.
9. *Id.* §2601(b)(2) ("[A]dequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment."); *see also id.* §§2604-2605.
10. *See id.* §2605(a)-(c).
11. *Id.* §2618.
12. *See* Consumer Product Safety Act of 1972, Pub. L. No. 92-573; 86 Stat. 1207 (Oct. 27, 1972), codified at 15 U.S.C. §2058 (mandating that consumer product safety rules impose "the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated").
13. 7 U.S.C. §§136-136*y*, ELR Stat. FIFRA §§2-35.
14. *See* 7 U.S.C. §136 (defining unreasonable adverse effects to include, in the case of non-food use pesticides, (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide"); 7 U.S.C. §2506 (requiring any consumer product safety rules to be "reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product").
15. *See* 7 U.S.C. §136n (Administrative Procedure; Judicial Review); 15 U.S.C. §2060 (Judicial Review of Consumer Product Safety Rules); 21 U.S.C. §360g (Judicial Review).

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

ucts ever regulated under a single statute. As EPA discovered through its 1979 TSCA inventory, the reported number of different chemical substances already in commerce by 1980 far exceeded those of other federal product regulatory programs at the time. *See* Table I. Yet, even at its inception, EPA faced critical challenges in obtaining funding commensurate with the task.

Table 1: Scope of Federally Regulated Substances in 1980s

Regulatory Programs in 1980s	Regulated Chemicals
Inventory of Chemical Substances in Commerce (TSCA)	65,000 (est.)[a]
Approved Food, Drug, and Cosmetic Additives (FFDCA)	<1,000[b]
Registered Pesticide Active Ingredients (FIFRA)	514[c]
Substances Subject to Permissible Exposure Limits (PELs) (OSHA)	475[d]
Approved Human Drugs (FFDCA)	9,374[e]

a Reflects preliminary results of initial inventory, as reported in EPA's 1980 budget summary (Jan. 29, 1979).

b Includes substances listed in the following sections of Title 21 of the 1980 Code of Federal Regulations (C.F.R.): 21 C.F.R. §171 (Food Additives); *id.* §172 (Secondary Direct Food Additives); *id.* §173-77 (Indirect Food Additives); *id.* §179 (Food Additives Permitted Pending Additional Study); *id.* §180 (Prior-Sanctioned Food Ingredients); *id.* §§181-184 (Food Substances Affirmed as Generally Recognized as Safe); *id.* §189 (Substances Prohibited From Use in Human Food); and *id.* §193 (Tolerances for Pesticides in Food) (1980).

c U.S. EPA, *1980 Congressional Budget Justification*, R-2 (Jan. 29, 1979).

d Includes substances identified in 1980 edition of 29 C.F.R. §1910 (Toxic and Hazardous Substances).

e Based on compiled list of approved new drug applications, 1938-1980. *See* FDA, Summary of NDA Approvals & Receipts, 1938 to the Present.

The challenge of obtaining the resources and staff necessary to implement TSCA's broad mandate became evident early in the implementation process. In 1978, a White House official testifying on the adequacy of EPA's budgetary and manpower resources reported:

> [TSCA] became effective January 1, 1979, and provided EPA with the major responsibility to require testing and to restrict the use of certain chemical substances. Resources have jumped dramatically since the Act passed. In fiscal year 1978, $29 million and 314 positions were available. We note that the 1979 budget requests a budget authority of $56.7 million and 573 positions.[16]

EPA never reached its 1979 budget goal, let alone the "6,000 positions and $200 million annually" estimate a former Administrator projected as necessary.[17] During the early phases of TSCA implementation, EPA struggled to fill the needed positions even when it had the resources and hiring authority.[18] Hiring difficulties aside, however, larger questions remained as to "whether EPA will have adequate resources to effectively carry out all TSCA responsibilities."[19] In a 1980 review of EPA's progress with the chemicals program, the General Accounting Office (GAO) cited EPA's own conclusion that the "[t]he resources available in the next few years do not begin to be adequate to meet the expected program needs; a conservative estimate of the number of people needed for the implementation stage appropriate to FY 1979 is on the order of 1,500, with no allowance for startup inefficiencies."[20]

Such calls for resources fell on deaf ears during the early years of the Reagan Administration, and, between 1981 and 1984, EPA's budget for chemical control activities under TSCA fell from $63 million to $37 million.[21] Staffing for chemical control and abatement efforts in EPA's Office of Toxic Substances also suffered, falling from 457 full-time employees in 1981 to 374 in 1984.[22] A 1984 GAO report offered a pessimistic review of EPA's TSCA implementation activities:

> Since [TSCA's] passage 7 years ago, EPA has regulated four chemicals. EPA has identified 60 existing chemicals, through its new assessment process, that may present an unreasonable risk and need to be evaluated to determine what, if any, regulatory controls are needed. EPA stated that resource constraints will result in only a few of these chemicals being considered for regulatory control each year.[23]

These budgetary and staff constraints not only hampered EPA's ability to tackle the larger backlog of existing chemicals awaiting preliminary review, they also restricted the Agency's ability to fund and staff the handful of chemical substance reviews EPA identified as priorities based on known risks. The true impact of the program's budget constraints finally hit home in 1991, when the U.S. Court of Appeals for the Fifth Circuit, in *Corrosion Proof Fittings v. EPA*,[24] issued a controversial decision vacating EPA's sweeping asbestos ban. EPA had initiated its review of asbestos in 1979, and, after 10 years, hundreds of studies, and thousands of papers of analysis, EPA concluded that asbestos posed an unreasonable risk to human health at all levels of exposure.[25] EPA's response was to ban most

16. GAO, *Adequacy of EPA's Budgetary and Manpower Resources in Carrying Out Its Mission*. Testimony of Henry Eschwege, Director, Community and Economic Development Division, Before the Subcommittee on Environmental Pollution, Senate Committee on Environment and Public Works (Jan. 30, 1978), 13-14, *available at* http://www.gao.gov/products/104810.
17. Testimony of Henry Eschwege, *supra* note 16 ("[T]he former Acting Administrator of EPA stated that he anticipated that within 5 to 10 years, the [TSCA] program would reach 6,000 positions and $200 million annually.").
18. By mid-May 1980, EPA had filled only 423 of its 510 authorized slots. *Id.*
19. *Id.*
20. *See* GAO, *Natural Resources and Environment: EPA Is Slow to Carry Out Its Responsibility to Control Harmful Chemicals*, CED-81-1 (Oct. 28, 1980), 11, *available at* http://www.gao.gov/products/CED-81-1. In 2004, GAO changed its full name to Government Accountability Office. Future references to GAO apply accordingly.
21. *See* CBO, EPA: Overview of the Proposed 1984 Budget (Apr. 1983), 40, *available at* https://www.cbo.gov/ftpdocs/50xx/doc5066/doc17a.pdf.
22. *Id.*
23. GAO, *Natural Resources and Environment: EPA's Efforts to Identify and Control Harmful Chemicals in Use*, RCED-84-100 (June 13, 1984).
24. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 22 ELR 20037 (5th Cir. 1991).
25. U.S. EPA, Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions; Final Rule, 54 Fed. Reg. 29460, 29461 (July 12, 1989).

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

commercial uses of asbestos within 10 years.[26] On review, the Fifth Circuit vacated the rule, citing procedural and substantive flaws in EPA's analysis.[27]

Procedurally, EPA had erred by adopting a new methodology for assessing certain risks without seeking adequate public comment.[28] Substantively, the court held that EPA had failed to consider the availability of less burdensome control strategies as alternatives to a complete ban, and had failed to assess the risks associated with potential substitutes for the banned material.[29] In addition, the court held that EPA had failed to adequately quantify long-term costs and benefits of the action, violating TSCA's mandate to consider "reasonably ascertainable economic consequences" of the action.[30]

For EPA and many in the environmental community, the lesson from *Corrosion Proof Fittings* was that §6 of TSCA was impractical, if not fatally flawed, as a risk-management tool.[31] Legal analysts have questioned whether the *Corrosion Proof Fittings* case was truly a referendum on the language of TSCA itself, a case of judicial overreach in a conservative circuit, or a simple rebuke of inadequate regulatory diligence by EPA. Considering the historic and chronic underfunding of EPA's TSCA program up to the time of the *Corrosion Proof Fittings* decision, perhaps it does not matter. The case confirmed what budget analysts already knew. EPA had neither the money nor the staff available to apply such a process-intensive, substantively complex, and legally vulnerable assessment framework to even a handful of existing chemicals.[32]

EPA largely abandoned the use of §6 risk-management authority to address existing chemical risks, focusing instead on pollution prevention and voluntary measures authorized by other sections of TSCA.[33] In 1991, the president's proposed TSCA budget had allocated $44.4 million and 382 staff to chemical testing and new and existing chemical-control activities.[34] By 1999, the numbers had fallen to $30 million and 270 staff.[35] As late as 2008, staffing for "core" TSCA programs remained below 300.[36]

This is not to say that EPA abandoned its Title 1 TSCA obligations entirely. EPA did, however, reduce its reliance on TSCA Title I in setting priorities, looking instead to voluntary initiatives and regulation under other legal authorities.[37] Thus, in lieu of issuing TSCA §4 test orders or rules, EPA initiated the high-production volume (HPV) challenge, a voluntary industry testing program addressing substances most commonly used in the United States.[38] In lieu of undertaking costly and legally vulnerable product-by-product risk-mitigation efforts, EPA moved toward a "pollution-prevention" regulatory strategy, focusing on reducing the inherent toxicity of substances used in commerce, regardless of the actual risks posed in any given case.[39]

If anything, Congress facilitated EPA's move toward a more triage-based approach to TSCA during the 1990s with the passage of several important bills. In 1986, Congress passed the Emergency Planning and Community Right-to-Know Act (EPCRA),[40] which included a requirement that chemical-intensive companies report annually on their storage, use, and release of certain substances, and that EPA create and publicize the resulting Toxics Release Inventory results. This new regulatory model proved appealing to EPA, as it avoided the expense and legal uncertainty associated with making risk-based chemical regulatory decisions under §6 of TSCA, while still allowing EPA to influence industry and consumer behavior through the market-shaping power of information to encourage, if not shame, regulated companies into using fewer toxic substances.[41] In 1990, Congress passed the Pollution Prevention Act of 1990, authorizing a variety of federal programs to encouraging pollution prevention and source-reduction activities. Resulting EPA programs like the Design for the Environment (DfE) program and the Environmentally-Preferable Purchasing (EPP) program encouraged businesses, consumers, and manufacturers to transition to less-toxic substances as a general philosophy, without requiring EPA to engage in costly product-by-product risk determinations.[42] In 1992, Congress passed the Lead-Based Paint Hazard Reduction Act, codified as Title IV of TSCA, directing EPA to establish health-based standards for a variety of lead-based paint hazards, and to mandate stringent lead-based paint notice-and-disclosure requirements associated with sales, leases, and renovations

26. *Id.* at 29461.
27. *Corrosion Proof Fittings*, 947 F.2d at 1226.
28. *Id.* at 1229 ("By depriving the petitioners of their right to cross-examine EPA witnesses on methodology and data used to support as much as eighty percent of the proposed benefits in some areas, the EPA also violated the dictates of TSCA.").
29. *Id.* at 1215-18.
30. *Id.* at 1213-20.
31. *See, e.g.*, *Statement of Richard A. Denison. Ph.D., Senior Scientist, Environmental Defense Fund*, U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, Hearing on Revisiting the Toxic Substances Control Act (Feb. 26, 2009), 2, *available at* http://www.edf.org/sites/default/files/9295_Denison_testimony_Toxics_Act_0.pdf.
32. GAO, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, Report to Congressional Requesters, GAO/RCED-94-103 (Sept. 1994) ("As a result of the court decision, EPA finds itself faced with the need to commit even more resources to any effort to regulate under section 6 and the possibility that the effort may not end in regulation.").
33. *See, e.g., id.* ("EPA Officials told us that with the court decision in the asbestos case, EPA most likely will not attempt to issue regulations under section 6 for comprehensive bans or restrictions on chemicals.").
34. *See* U.S. EPA, Summary of 1992 Budget, 31-33 (Feb. 1991).
35. *See* 2011 ELR TSCA Implementation Paper, *supra* note 3, at 10542.
36. *Id.*
37. *Id.* at 10533.
38. 2011 ELR TSCA Implementation Paper at 10533-34; *see also* U.S. EPA, *High Production Volume (HPV) Challenge*, *available at* http://www.epa.gov/hpv/.
39. *See, e.g.*, National Performance Review, *2003 Phase II Report; Creating a U.S. Environmental Protection Agency That Works Better and Costs Less*, 2000ANRW (2003) ("EPA must make shift toward pollution prevention and away from pollution control.").
40. *See, e.g.*, EPCRA, 42 U.S.C. §§11001-11050, ELR Stat. EPCRA §§301-330, in particular 42 U.S.C. §11023 (establishing the Toxics Release Inventory reporting program).
41. *See. e.g.*, Charles Franklin, *From Risk Management to Risk Perception: The Evolution of Right-to-Know Policy,* Daily Env't Rep. (BNA), 124 DEN B-1 (06/27/2013), 2-5.
42. Pollution Prevention Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388-321 et seq.) (Nov. 5, 1990).

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

of older housing.[43] One need not question the utility of these programs to recognize that, during times of stagnant or shrinking federal budgets, new priorities only lessened the resources available for core TSCA programs.

III. TSCA Gets a Second Look

The 2008 election of President Barack Obama, and his selection of Lisa Jackson as EPA Administrator, signaled a potential shift in TSCA's fortune. Confirmed by the Senate in January 2009, Jackson quickly signaled her interest in revisiting TSCA, both from a legislative and administrative perspective, stating:

> More than 30 years after Congress enacted [TSCA], it is clear that we are not assessing and not doing an adequate job of and managing the risks of chemicals in consumer products, the workplace and the environment. It is now time to revise and strengthen EPA's chemicals management and risk assessment programs.[44]

The Administration subsequently introduced a series of regulatory proposals to reinterpret EPA's testing and risk-management authorities, to tighten oversight of confidential business information claims, and to increase the scrutiny on existing chemicals.[45] In September 2009, EPA released a list of Essential Principles for Reform of Chemicals Management Legislation, including the principle that implementation of the law "should be adequately and consistently funded."[46] Administrator Jackson sought modest increases to EPA's budget for core TSCA implementation as well, although not at levels large enough to materially change EPA's regulatory capacity.[47] On Capitol Hill, a small but energetic group of Democratic lawmakers introduced several TSCA reform bills between 2010 and 2012.[48] While these bills and related hearings prompted some dialogue on the issue of chemical control reform, progress remained unlikely given the partisan divide within and among the two chambers.

Despite the extensive record illustrating the lack of adequate funding for EPA's core TSCA programs, even the most recent calls for modernization or reform have given limited attention to the budgetary implications of an expanded regulatory mandate. For example, as of late-April 2014, the Congressional Budget Office (CBO) had yet to score any of the pending TSCA reform bills introduced during the 113th Congress, but its budget estimate for an earlier 2011 bill raises concerns about the CBO's own appreciation of the resource demands for meaningful reform.[49] The Safe Chemicals Act of 2011, S. 847, would have adopted many of the same regulatory requirements used under the smaller, but more heavily funded federal pesticide regulatory program, including minimum data sets, premarket review and approval for new substances, evaluation against a "reasonable certainty of no harm" standard, and consideration of both aggregate and cumulative exposure pathways.[50] Despite the significant increases to the scope of EPA's obligation proposed under the law, the CBO estimated that "implementing this legislation would cost $128 million over the next five years," or less than $30 million a year in additional funding.[51] Such limited increases would likely be inadequate to improve the current TSCA's implementation, let alone a scaled-up program of the type proposed in 2011.

Recent hearings have done little to clarify the cost and financing implications of an expanded chemical control regime. During a November 2013 hearing before the Environment and the Economy Subcommittee of the House Energy and Commerce Committee, congressional members questioned Jim Jones, the EPA Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances (OPPTS), about the level of resources required to support an expanded TSCA program.[52] Jones offered nuanced, if understated, responses:

> In the absence of additional resources, EPA's rate of progress would be meaningfully constrained.[53]
>
> Under existing funding, we would be limited in how much progress we could make at any one time.[54]
>
> We would run into issues with expectations.[55]
>
> [T]he number of assessments we would be able to do under existing resources would probably, for most people, be considered to be [in]adequate.[56]

Asked how a new law should finance the costs associated with an expanded review program, Jones alluded to "models out there that involve the industry financing that are used in the FDA [Food and Drug Administration] and our pesticides program that are worth looking at."[57]

---

43. Residential Lead-Based Paint Hazard Reduction Act of 1992, Pub. L. No. 102-550, 106 Stat. 3910 (Oct. 28, 1992).
44. Lisa Jackson, *Opening Memo to Employees* (Jan. 23, 2009), *available at* http://blog.epa.gov/administrator/2009/01/26/opening-memo-to-epa-employees/.
45. Press releases from some of EPA's more prominent TSCA regulatory initiatives between 2009 and present are available at http://www.epa.gov/oppt/opptnew.html (last visited Apr. 3, 2014).
46. U.S. EPA, *Essential Principles for Reform of Chemicals Management Legislation* (Sept. 29, 2009), *available at* http://www.epa.gov/oppt/existingchemicals/pubs/principles.html.
47. U.S. EPA, FY 2012 Budget in Brief (Feb. 2011) and FY 2013 Budget in Brief (Feb. 2012).
48. Linda-Jo Schierow, *Proposed Amendments to the Toxic Substances Control Act (TSCA): Senate and House Bills Compared With Current Law*, Congressional Research Service (Aug. 12, 2010).
49. *See* CBO, *Congressional Budget Office Cost Estimate: S. 847, Safe Chemicals Act of 2011*, as reported by the Senate Committee on Environment and Public Works (Oct. 1, 2012) [CBO 2011 Analysis].
50. *See* S. 847, *Safe Chemicals Act* (introduced July 15, 2011).
51. CBO 2011 Analysis at 1.
52. *See* Transcript of Testimony of James Jones, Office of Chemical Safety and Pollution Prevention, EPA, Before the House Committee on Energy And Commerce United States, Subcommittee on Environment and the Economy Nov. 13, 2013), *available at* http://democrats.energycommerce.house.gov/sites/default/files/documents/Preliminary-Transcript-EE-S-1009-Chemical-Safety-Improvement-Act-2013-11-13.pdf [hereinafter Jim Jones Testimony].
53. *Id.* at 61, line 1415.
54. *Id.* at 39-40, line 1415, lines 784-85.
55. *Id.* at 80, lines 1753-54.
56. *Id.* at 61, line 1756-85.
57. *Id.* at 80, line 1759-61.

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

The next section takes up Assistant Administrator Jones' challenge and looks to EPA's pesticide regulatory program and FDA's human drug approval program for insight into the potential resource costs associated with comprehensive, state-of-the-art chemical regulatory reform.

IV. Learning From the Struggles and Successes of Others

A. *Federal Regulation of Pesticides*

Prior to 1972, federal pesticide regulation was limited, and focused more on ensuring the efficacy of the products being marketed than on ensuring their safety to human health and the environment.[58] In 1970, President Richard Nixon created EPA, and two years later, spurred by the growing environmental movement and public concern over pesticide safety in the wake of Rachel Carson's seminal 1961 book, *Silent Spring*, Congress made significant changes to the federal pesticide regulatory system.[59]

The 1972 Amendments increased the scope of federal pesticide regulation, requiring all pesticides and pesticide labeling to be reviewed and registered by EPA, based on an affirmative determination that the pesticide would not cause "unreasonable adverse effects on the environment" when used in accordance with widespread and commonly recognized practice.[60] The amendments authorized EPA to develop premarket data requirements for new products, and issue data call-ins for existing products specifying "the kinds of information . . . required to support the registration of a pesticide and establish a procedural framework for ensuring that data developers obtain compensation from parties seeking to use that data."[61] The amendments also directed EPA to review existing registrations every five years and established procedures for EPA to suspend or cancel previously registered pesticides, based on a determination of noncompliance or where the pesticide caused unreasonable adverse effects.[62] Early on in the implementation process, EPA struggled to make headway with the increased scope and burden of its mandate.[63]

Frustrated with the slow pace, Congress took additional efforts in 1978, 1980, and 1988 to bolster EPA's risk-management authority and mandate more-prescriptive processes and time lines for "reregistration" of older pesticides against newer standards.[64] Significantly, the 1988 Amendments also granted EPA authority to charge pesticide registrants a variety of fees for registration and maintenance of active ingredients, and allowed EPA to use collected proceeds to fund its efforts to reregister older pesticides—a tacit recognition of the significant resource cost associated with the review process.[65]

Even with this new funding source, however, EPA was unable to meet the deadlines set by Congress with its existing resources.[66] EPA continued to struggle under the weight, complexity, and cost of the reregistration task. In testimony before Congress in 1993, a GAO official testified that five years after Congress had directed EPA to complete reregistration of the 20,000 existing pesticides in 10 years, EPA had addressed only 250 substances.[67] While GAO cited a variety of strategic and administrative reasons, GAO concluded that "[r]eregistration has not proceeded on schedule because EPA did not take into account the complexity and magnitude of the reregistration task or the resources needed to conduct the program."[68]

In 1996, Congress acted again to strengthen the pesticide program, spurred by a series of high-visibility food-safety scares and industry's desire to resolve inconsistencies in the regulation of processed and raw agricultural products. The 1996 Food Quality Protection Act (FQPA) made significant changes to both FIFRA and the portions of FFDCA governing pesticide residues on foods, mandating more-detailed safety reviews under aggressive deadlines.[69] FQPA set a 10-year deadline for

58. *See, e.g.*, Federal Insecticide Act of 1910, 36 Stat. 331, 331-33 (1910) (regulating insectides and fungicides to ensure adherence to claimed strength or purity claim, prevent ingredient substitution or abstraction, and where use would be "injurious to such vegetation when used"); FIFRA, *supra* note 13, §§165-168) (requiring the U.S. Department of Agriculture (USDA) to review and register economic poisons based on strength, purity, and adequacy of labeling, including required directions for use, and, where any substance is present in quantities highly toxic to man, appropriate warning labeling.). Congress did address the issue of pesticide residues from food-use pesticides on raw agricultural commodities in 1954 (Federal Food, Drug, and Cosmetic Act Amendments Act of 1954, 68 Stat. 511 (July 22, 1954)) and for processed foods in 1958 (Federal Food, Drug, and Cosmetic Act Amendments Act of 1958, 85 Pub. L. No. 929, 72 Stat. 1784 (July 22, 1958)).
59. Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973 (1972).
60. *Id.* at 979-80.
61. *Id.*
62. *Id.* at 984 (Section 6. Administrative Review: Suspension).
63. *See, e.g.*, GAO, *Report by the Comptroller General, Delays and Unresolved Issues Plague New Pesticide Protection Programs*, CED-80-32 (Feb. 15, 1980); GAO, *Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks*, RCED-86-125 (Apr. 1986) ("At its current pace, EPA's reassessment and reregistration efforts will extend into the 21st century due to the magnitude and complexity of the tasks involved.").
64. *See* Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 819 (1978); 1980 Federal Insecticide, Fungicide, and Rodenticide Act Amendments, Pub. L. No. 96-539, 94 Stat. 3194 (1980); Federal Insecticide, Fungicide, and Rodenticide Amendments of 1988, Pub. L. No. 100-532, 92 Stat. 2654 (1988).
65. *See* 1988 Amendments, 92 Stat. at 2663-67.
66. *See, e.g.*, GAO, Pesticide Reregistration May Not Be Completed Until 2006, RCED-93-94 (May 21, 1993) ("When FIFRA '88 was enacted, EPA anticipated that the accelerated reregistration program would cost about $260 million over 9 years. However, this initial cost estimate was not based on complete program costs."); GAO, *Pesticides: 30 Years Since* Silent Spring*—Many Long-Standing Concerns Remain,* T-RCED-92-77 (July 23, 1992) [hereinafter July 1992 GAO Report] (citing limited progress in reviewing older pesticides in light of current scientific knowledge and standards, difficulties in removing pesticides that are a cause for concern from the marketplace, and holes in the safety net designed to provide an early warning of pesticide dangers).
67. GAO, *Pesticides: Reregistration Delays Jeopardize Success of Proposed Policy Reforms*, Statement of Peter F. Guerrero, Resources Community and Economic Development Division, Before the Subcommittee on Environment, Energy, and Natural Resources, Committee on Government Operations, House of Representatives, GAO/T-RCED-94-48 (Oct. 29, 1993).
68. *Id.* at 3.
69. *See* Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (Aug. 3, 1996). For a detailed analysis of FQPA's changes to the federal pesticide regulatory system, see, e.g., U.S. EPA, *The Food Quality Protection Act (FQPA) Background*, *available at* http://www.epa.gov/

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

EPA to complete its review of all remaining older pesticide registrations and the 10,000 tolerances (e.g., pesticide residue limits) established for food-use pesticides.[70] Importantly, the law also recognized that these reforms would require significant increases in EPA's reregistration budget, giving EPA expanded authority to collect registration fees, and dedicating these fees to use in funding and staffing EPA's reregistration effort.[71]

But if the FQPA made important substantive legal improvements to federal pesticide law, it took several additional laws to bring critical procedural improvements. In 2004, Congress strengthened the financial stability of EPA's pesticide program by passing the Pesticide Registration Improvement Act (PRIA) as part of a larger omnibus bill.[72] Crafted with the involvement and support of pesticide manufacturers and stakeholders seeking to increase the predictability and responsiveness of EPA's pesticide review process, PRIA authorized EPA to impose pesticide registration service fees and specific review timeframes for 90 different types of registration actions, mandated specific time frames for covered pesticide reviews, and made other improvements to EPA's process for reviewing industry submissions.

In 2008, Congress reauthorized PRIA, expanding the number of registration fee categories from 90 to 140, changing the fee payment process, and establishing a 21-day application "pre-screening" process to help flag any deficiencies with an application package early on in the process, and authorizing grants to support worker protection, applicator training, and other partnership grants.[73] Congress reauthorized PRIA again in 2012, bringing the number of fee categories to 189, establishing new label review procedures, refining the "preliminary technical screening" step in the application review process, and authorizing additional funds for worker safety and partnership grants.[74]

The transition to partial program funding through user fees appears to have paid off for both EPA and the pesticide stakeholder community. Describing the impact of the PRIA process in 2011, then-Administrator Lisa Jackson explained:

> Before PRIA, because of limited resources, the Agency could not process all of the applications it received in a timely fashion. Large backlogs developed, and applicants could not predict when the Agency would make a decision. . . . With the additional resources provided by PRIA, however, the Agency can now process new applications in a timelier manner.
>
> In fact, since the start of the PRIA user fee program, EPA has met the time frames for more than 99% of PRIA applications.[75]

A prominent coalition of pesticide manufacturers described the PRIA funding model as a "win-win-win proposition [in which] EPA gets long-term stable funding, environmental and farm worker communities get increased funding for worker protection and increased funding for registration review, and industry benefits from predictable time lines for bringing newer products to market."[76] The move to pesticide user fees has even received guarded support from environmental advocacy groups like the Natural Resources Defense Council (NRDC), which see adequate funding as a necessary prerequisite to effective government oversight. In a 2008 press release on the renewal of PRIA in 2007, NRDC characterized the bill as "a huge win for both public health and the environment."[77]

Today, a registrant seeking regulatory review of a new or existing active ingredient, pesticide product, or label claim has access to clear guidelines governing the data requirements,[78] registration fees,[79] and review time frames[80] required for any given action. The fees and review times, like the data requirements, will differ significantly based on the type and complexity of action, with registrations of new, conventional, food-use active ingredients at one end of the spectrum (with fees of up to $570,000 and 24-month review periods) and minor regulatory amendments data submissions, and label changes with minimal fees and review times of three months or fewer.[81]

The success of PRIA 1, 2, and 3 suggests that it is possible to use fee-based funding to improve both regulatory performance and stakeholder satisfaction for a consumer regulatory program. Of course, the issues of what constitutes a reasonable fee, reasonable review time, and reasonable data requirements will always be challenging negotiation points for regulators and stakeholders in developing such a program. One reason the fee-based system has worked for the pesticide program, however, is that throughout legislative development and regulatory implementation process, Congress and EPA worked closely with manufacturers and public interest groups to ensure a workable, politically acceptable program. Such multi-stakeholder engagement

pesticides/regulating/laws/fqpa/backgrnd.htm.

70. FQPA, 110 Stat. §1434 (codified at 7 U.S.C. §346a(q)).
71. *Id.* §1536 (codified at 7 U.S.C. §136a-1(i)).
72. *See Consolidated Appropriations Act*, Pub. L. No. 108-199, 118 Stat. 3, 419 (Jan. 2003), codified at 7 U.S.C. §136W-8.
73. *Pesticide Registration Improvement Renewal Act of 2007*, Pub. L. No. 110-94, 121 Stat. 1000 (2007) [hereinafter PRIA2].
74. *Pesticide Registration Improvement Extension Act of 2012*, Pub. L. No. 112-177, 126 Stat. 1327 [hereinafter PRIA3].
75. Testimony of Lisa Jackson, Administrator, U.S. EPA, Before the House Committee on Agriculture (Mar. 10, 2011), 5.
76. Consumer Specialty Products Association (CSPA), *Press Statement: CSPA and the PRIA Coalition Acknowledges Congress' Renewal of the Pesticide Registration Improvement Act* (Sept. 16, 2012), *available at* http://www.cspa.org/news-media-center/news-releases/2012/09/cspa-and-the-pria-coalition-acknowledges-congress%E2%80%99-renewal-of-the-pesticide-registration-act/#sthash.QLHSKG9A.dpuf.
77. NRDC, *Press Release: Landmark Pesticide Registration Act Renewed by Congress: Bill Requires Pesticide Registration for the Next 5 Years*, Environmental News: Media Center (Sept. 24, 2007), *available at* http://www.nrdc.org/media/2007/070924.asp.
78. *See, e.g.*, U.S. EPA, *Pesticide Registration: Data Requirements Checklist*, *available at* http://www2.epa.gov/pesticide-registration/data-requirements-checklist.
79. U.S. EPA, Pesticide Registration Improvement Extension Act (PRIA 3) Tables—FY 2014/15 Fee Schedule for Registration Applications, *available at* http://www.epa.gov/pesticides/fees/tool/category-table.html.
80. *Id.*
81. *Id.*

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

will be just as critical for any effort to develop fee-based systems under any TSCA reform bill.

B. Federal Regulation of Human Drugs

The regulatory framework supporting federal oversight of human drugs, another niche form of chemical substance regulation, is equally impressive and even more costly. FDA regulates the manufacture, distribution, and sale of human drugs under the FFDCA, as amended extensively over 70 years.[82] As with food-use pesticides, federal law holds human drugs to higher scrutiny and a more-stringent premarket review standard than most other substances in commerce, reflecting the unique hazard and exposure considerations associated with a class of chemicals intentionally introduced onto or into the human body for the purpose of having a physiological effect. Because hospitals, doctors, and individual patients rely on these drugs to protect or to improve human health, and because the risks to human health from approval of a toxicologically "safe" but pharmacologically ineffective drug are so significant, drug manufacturers must also submit extensive efficacy testing in accordance with detailed federal requirements.

Federal oversight of the pharmaceutical industry originated during the early 20th century. In 1906, Congress passed the Food and Drugs Act, prohibiting interstate commerce in misbranded and adulterated foods, drinks, and drugs.[83] As with early regulation of pesticides, the primary focus of federal oversight was ensuring the strength, quality, and purity of substances making pharmaceutical claims rather than the inherent safety or efficacy of the products themselves.[84] In 1912, however, responding to the continued growth of quack medicines and false claims, Congress amended the Act to prohibit false therapeutic claims.[85]

In 1938, following the tragic death of more than 100 people from a would-be "wonder drug" analogous to antifreeze, Congress replaced the Food and Drugs Act with the FFDCA. The FFDCA required premarket review of new drugs by the FDA, made it easier for regulators to crack down on misbranded drugs, and granted the FDA additional enforcement authority.[86] As part of the premarket review process, manufacturers were required to provide "full reports of investigations which have been made to show whether or not such drug is safe for use."[87]

In 1962, Congress again enacted significant changes to the drug provisions of the FFDCA, responding, in part, to the tragic reports outside the United States of birth defects resulting from the use of the morning sickness drug Thalidomide during pregnancy.[88] The 1962 Amendments required new-drug manufacturers to demonstrate both the efficacy and safety of their products during the premarket review process, gave the FDA greater authority to establish data requirements in support of safety findings, and required the use of good manufacturing practices in drug development.[89] Unfortunately, the increased federal regulatory authority also increased budgetary and staff needs within the FDA, a situation exacerbated during periods of tight budgetary conditions at the administrative level.

Then, in 1992, Congress enacted the Prescription Drug User Fee Act (PDUFA), authorizing the FDA to collect fees from companies that produce certain human drug and biological products, and mandating that such fees be directed toward drug and biologic reviews.[90] The legislation, crafted with the support of industry stakeholders eager for a more-responsive drug process, required new drug and biologic applicants to pay application fees upon submittal, and also charged imposed fees based on the number of regulated products in commerce and the number of regulated establishments. The results were notable, with median review times showing documented reductions.[91] The FDA noted the impact of the new fee structure in an FDA backgrounder in 1997:

> In the past five years, [PDUFA] has enabled the agency to reduce to 15 months the 30-month average time that used to be required for a drug review before PDUFA. This accomplishment was made possible by FDA managerial reforms and the addition of 696 employees to the agency's drugs and biologics program, which was financed by $329 million in user fees from the pharmaceutical industry.[92]

Congress has reauthorized PDUFA's fee structure three more times since 1997, and while the increased reliance on user fees created funding challenges for certain FDA functions outside of the PDUFA's scope, it is credited with improving the efficiency and speed of the U.S. drug approval process.[93] In 2012, Congress expanded the

82. *See* 21 U.S.C. §§351-360eee4 (2014).
83. *See* Pure Food and Drug Act, 59 Pub. L. No. 384, 34 Stat. 768 (1906).
84. *Id.* Also reminiscent of early federal pesticide regulation, the USDA retained oversight of the FDA until 1940. Wallace F. Janssen, *About FDA: The Story of the Laws Behind the Labels*, FDA Consumer (June 1981).
85. Pure Food Act, Pub. L. No. 62-301, 37 Stat. 416 (Aug. 23, 1912) (defining as misbranded drugs where "its package or label shall bear or contain any statement design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent").
86. Federal Food, Drug, and Cosmetic Act (FFDCA), Pub. L. No. 75-717, 52 Stat. 1040 (June 25, 1938). For an excellent overview of the history of the development of federal food, drug, and cosmetic law, visit http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm.
87. *Id.* at 1052.
88. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (Oct. 10, 1962).
89. *Id.* at 781-85.
90. Prescription Drug User Fee Act, 102-571, 106 Stat. 4491 (Oct. 29, 1992); *see also* Susan Thaul, *The Prescription Drug User Fee Act (PDUFA): Background and Issues for PDUFA IV Reauthorization*, Congressional Research Service (June 27, 2008).
91. *See* Janet Woodcock, M.D. & Suzanne Junod, Ph.D., *PDUFA Lays the Foundation: Launching Into the Era of User Fee Acts*, FDA.gov, *available at* http://www.fda.gov/aboutfda/whatwedo/history/overviews/ucm305697.htm.
92. FDA, *Backgrounder on FDAMA*, FDA.gov, *available at* http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDAMA/ucm089179.htm.
93. *See, e.g.*, GAO, *Food and Drug Administration: Effect of User Fees on Drug Approval Times, Withdrawals, and Other Agency Activities,* GAO-02-958 (Sept. 17, 2002); Food and Drug Administration: GAO, *FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs*, GAO-09-581 (June 19, 2009).

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

FDA's use of user fees to support its generic drug review obligations.[94] Congress has also expanded its user fee system to address regulatory obligations in other areas of its jurisdiction.[95]

V. Opportunities and Lessons for a Second Chance

The prospects for meaningful TSCA reform improved significantly in May 2013, with the introduction of the Chemical Safety Improvement Act by a bipartisan team of lawmakers led by the late Sen. Frank Lautenberg (D-N.J.) and Sen. David Vitter (R-La.).[96] Although the furtive nature of its initial development created some consternation within some traditional stakeholder camps, the bill accomplished an important goal—starting an actual bipartisan dialogue on TSCA reform. Republican and Democratic lawmakers in both houses began holding hearings, markups, and meetings with stakeholders to assess opportunities for bipartisan reform.[97] As this Article goes to print, three different chemical control bills are on the table, providing a range of visions for reform, and staff in both houses are reportedly working behind the scenes to find common ground.[98]

Consensus and compromise will not come easily. As with any complex piece of legislation, TSCA and its would-be successor bills reflect hundreds of intricate policy choices involving law, science, technology, economics, politics, geography, and history. How much data is enough? How much risk is too much? How much uncertainty is acceptable? What is the definition of "safe"? What is the definition of reasonable? Who bears the burden of proof? These are not yes-or-no questions, and the public record is replete with papers, arguments, and opinions on the many arcane issues of regulatory and science policy raised by TSCA reform.

This Article does not attempt to address the expansive and arcane list of policy points driving much of the current policy debate. It can, however, offer a few basic lessons from TSCA's own history, and that of its other, more successful sister statutes, on the issue of resources.

A. *Science-Based Substance Regulation Is Expensive*

Put simply, developing and maintaining a first-class, risk-based substance or product regulatory system, particularly one with the breadth and scope envisioned by Congress for TSCA, is an expensive undertaking. That expense, moreover, will have to be shared by the private and public sector.

Again, federal pesticide and drug law illustrate the challenge. On the front end, long before a company brings a new pesticide or drug active ingredient to the federal government for approval, it will spend years and millions of dollars on testing and development. In 2011, EPA estimated that the cost to generate the data required to support a new conventional pesticide active ingredient registration in the United States ranged from $4.3 million to $10 million, depending on the nature of the product and its uses.[99] Food use pesticides, regulated under the heightened safety requirements of the FFDCA, are particularly costly.[100] The testing costs for pesticides pale in comparison to the cost to support a new drug application. According to one analysis cited by *Forbes* magazine in 2013, "[a] company hoping to get a single drug to market can expect to have spent $350 million before the medicine is available for sale." Because of the high failure rate for new drugs, the report noted, "large pharmaceutical companies that are working on dozens of drug projects at once spend $5 billion per new medicine."[101]

Once pesticide or drug applicants have developed the detailed technical dossiers necessary to support their application, the burden (and cost) shifts to the government for review. This process too is costly. Multidisciplinary teams of federal regulators (or contractors overseen by federal staff) review the data dossiers against detailed regulations, science policies, and technical standards. These reviews, like the regulatory proceedings required to develop the underlying policies, are time-intensive and require staff with a diverse array of scientific, technical, economic, and legal skills.[102]

To support these review obligations, both EPA and the FDA maintain large programmatic budgets and rosters of federal staff. For 2012, for example, EPA's Office of Pesticide Programs budgeted approximately 828 staff and roughly $115 million[103] to register 118 new active ingredients, to update safety findings for 70 active ingredients currently

94. Generic Drug User Fee Amendments of 2012, Pub. L. No. 112-144, 126 Stat. 993 (July 9, 2012).

95. *See* FDA, *For Industry: User Fees*, FDA.gov, http://www.fda.gov/ForIndustry/UserFees/ (last visited Apr. 7, 2014).

96. S. 1009, Consumer Safety Improvement Act (introduced May 22, 2013), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-113s1009is/pdf/BILLS-113s1009is.pdf.

97. *Id.*

98. In addition to S. 1009, pending bills include S. 696, Safe Chemicals Act of 2013 (introduced Apr. 10, 2013), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-113s696is/pdf/BILLS-113s696is.pdf; House Discussion Draft, *Chemicals in Commerce Act*, released Feb. 27, 2014, *available at* http://docs.house.gov/meetings/IF/IF18/20140312/101890/BILLS-113pih-ChemicalsinCommerceAct.pdf.

99. *See* John Faulkner & T.J. Wyatt, *Estimating the Data Generation Costs for Registration of a New Conventional Pesticide Active Ingredient*, Biological and Economic Analysis Division, OPP, U.S. EPA (Oct. 2011), *available at* http://www.epa.gov/pesticides/ppdc/2011/october/new-conventional.pdf. EPA has developed separate programs for antimicrobial and biopesticides, and the figures may differ.

100. *See, e.g.*, Croplife America, Pesticide Regulation, http://www.croplifeamerica.org/crop-protection/pesticide-regulation. *See also* Purdue University, *The Pesticide Marketplace: Discovering and Developing New Products*, Purdue Extension, PPP-71 (June 2006) ("It takes eight to ten years and millions of dollars to test, develop, and register a new pesticide once a promising compound is discovered.").

101. *See* Mathew Harper, *The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change*, Forbes Mag. (Aug. 11, 2013), http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/ (last visited Apr. 8, 2014).

102. *See, e.g.*, 40 C.F.R. §§150-180 (Pesticide Programs); *see also* EPA's Pesticide Registration Manual web page, *available at* http://www2.epa.gov/pesticide-registration/pesticide-registration-manual (last visited Mar. 25, 2014).

103. *See* U.S. EPA, 2013 Budget (based on Science and Technology (S&T) and Environmental Programs & Management (EPM) line items only).

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

in commerce, and to process roughly 4,500 registration or label changes.[104] The FDA's proposed 2012 drug budget, including user fees, was significantly higher at $1.55 billion and 4,503 staff.[105] The FDA projected it would receive 124 new drug applications (NDAs), issue approval decisions for approximately 87 NDAs, and process 3,000 changes for roughly 6,500 FDA-approved drugs.[106]

Considering the 2012 budget and staffing figures for EPA's pesticide program and the FDA's drug program, summarized in Table 2, the resources allocated for the much larger universe of new and existing TSCA-regulated substances appear remarkably paltry.

Table 2: 2012 Budget, FTE, and Performance Statistics for Federal Drug, Pesticide, and Chemical Regulatory Programs Offices*

Regulatory Program	New Substances 2012	Total Regulated Substances	Existing Substances Actions 2012	2012 Staff	2012 Budget
Human Drug (FDA)**	87 New Drug Applications	6,543***	3,000 supplemental amendments	4,503	$1.55 billion
Pesticide (EPA)	118 Active Ingredients	800-1,100	70 reviews 1,450 registration actions	828	$117 million
Chemical Review (EPA)****	1,000 Premanufacture Notices	10,000-84,000*****	7 chemical action plans	243	$56.5 million

* Numbers drawn from the Administration's 2012 Congressional Budget Justifications for each Agency. These numbers are only a sample of the funds and staff dedicated to the above-referenced issues, and does not account for field staff, enforcement, many scientific and research activities, and other items not reflected in organizational budget estimates.

** Based on human drug resources only and excludes numbers for biologics, animal drugs, devices, etc.

*** Based on a compilation of approved active ingredients, referenced at Drugs@FDA.com (last visited Mar. 25, 2014).

**** Excludes resources devoted to special programs for lead, PCB, mercury, and asbestos control; Design for the Environment and other pollution prevention programs, and testing and review of chemicals identified for review through EPA's Integrated Risk Information System (IRIS).

***** Range reflects the fact that the current TSCA inventory identifies the universe of existing chemicals as roughly 84,000, but there are questions as to how many of this number are actually in practical commerce today.

Improvement to the federal chemical regulatory system will require more than just a new law; it will require a larger, consistent supply of money and federal staff to carry out the essential government duties associated with regulating the massive chemical industry. This is especially the case if lawmakers are looking to strengthen the regulatory standards for regulated chemicals and industries. Indeed, impressive as the budgets and staff levels may appear for federal pesticide and drug programs in 2012, the resources would still be inadequate if Congress applied the stricter substantive and procedural standards of the FFDCA or FIFRA to the 1,000 or more new chemicals submitted every year and the more than 60,000 grandfathered chemicals awaiting review.

B. If Every Substance Is a Priority, None Is a Priority

While the federal drug and pesticide programs are useful reference points, there are compelling risk-based reasons not to treat every chemical substance like a pesticide or human drug. Federal pesticide safety law governs a class of chemical substances intended to kill, destroy, or repel living organisms, often present in agricultural, household, commercial, and consumer environments. Federal drug safety law governs a class of chemical substances destined for intentional use and exposure to human beings, in forms and concentrations expressly intended to have a physiological effect. The implicit hazard and/or exposure potential from these classes of chemicals (and, for drugs and some pesticides, the public health importance of ensuring that they are effective as claimed) makes them logical candidates for priority scrutiny and review.

TSCA is different in numbers, scope, and kind. Of the more than 80,000 substances on the TSCA inventory and the 1,000 or more new substances submitted each year, some may match or exceed the hazard, exposure, and efficacy risk justifications driving drug and pesticide regulatory policy, but many more will not. Without a manageable and coherent process for establishing data requirements and setting priorities for regulatory review, Congress will never allocate the level of resources required to conduct a timely review of the tens of thousands of substances already in commerce, let alone the 1,000 or more new substances introduced each year. Many of the new chemicals coming to market today are the reduced-risk alternatives to the substances of yesterday, and a one-size-fits-all review process that treats every substance like a high-hazard, high-exposure poison is more likely to delay the introduction of safer chemicals.

In short, the sheer number of substances regulated under TSCA dictates the need for a more flexible, risk-based process to screen and prioritize regulatory action than exists under FIFRA or the FFDCA today. The challenge for policymakers is to craft a chemical regulatory system for this large, heterogeneous universe of chemicals that provides EPA the flexibility to adjust both the front-end data

104. *See* U.S. EPA, Office of Pesticide Programs, *Pesticide Registration Improvement Renewal Act (PRIA 2) Fee Category Interpretations—Fiscal Year 2011/ 2012* (Sept. 15, 2010).

105. *See* Department of Health and Human Services, Food and Drug Administration, *Fiscal Year 2012 Justification for Estimates for Appropriations Committees*, at 89.

106. *See id.* at 174; for the estimated number of current approved drugs, see FDA, *Database of FDA Approved Drug Products*, *available at* http://www.accessdata.fda.gov/Scripts/cder/drugsatfda/index.cfm.

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

requirements and the government review process in a manner commensurate with the risk.

C. User Fees Are More Scalable Than Appropriations

A common theme in the early development of federal pesticide, drug, and chemical regulatory programs is the struggle that regulators faced in matching their appropriated budgets and staff levels to the ever-changing demands of their industry and the market in general. For the drug and pesticide sectors, frustration over the regulatory delays resulting from chronic resource constraints prompted policymakers, industry stakeholders, and others to agree on the need for a fee-based system that would align each agency's funding source to the nature and scope of the regulatory tasks at hand. Today, both EPA and the FDA, with the help and support of industry, have developed fee-based funding systems that have significantly improved the responsiveness of their review systems.

In 2012, for example, the FDA's program budget for human drug activities alone totaled $1.55 billion and 4,503 staff positions. Of that funding, $600 million and 2,310 staff positions were made possible through various user fees. The FDA projected that the funding and staff provided by the newly enacted Generic Drug User Fee alone would reduce the median time for generic drug reviews from 27.5 months in 2010 to 17.5 months in 2012.[107] In 2012, EPA's FIFRA program collected $15.6 million in registration fees and $22 million in maintenance fees.[108] Both agencies have developed detailed fee schedules tailored to the wide variety of regulatory actions required to support day-to-day operation of the regulatory programs.

In contrast, TSCA continues to rely on the largesse of the appropriations process for its funding, a process that has worked to its detriment since the beginning of the chemical control program.

D. A Fee-Based System Will Require Investments in Technology

Establishing a fee-based funding system for the large universe of chemical substances within TSCA's scope will pose some unique challenges. Because the federal pesticide and drug regulatory programs regulate their respective substances with such high levels of scrutiny (at the active ingredient, formulation, and product level), the process of identifying regulated parties and assessing the relevant fees is likely to be more straightforward in those cases than it will be for the larger, more diverse universe of commercial chemicals and chemical products potentially subject to regulation under a TSCA-like statute. Pesticide and drug manufacturers are regulated at the active ingredient, formulation, and product level, and virtually any change to an ingredient, product, or label requires the regulated community to engage with the regulator to provide notice or obtain approval.

The current TSCA regulatory framework does not provide the same readily identifiable opportunities for product-level scrutiny. Still, Charlie Auer, a former Director of EPA's Office of Pollution Prevention and Toxics, has suggested using EPA's Chemical Data Reporting (CDR) program as a framework for coordinating with regulated entities on fee-related issues.[109] Auer suggests:

> [R]equiring regular periodic reporting . . . throughout the chain of commerce from manufacturers to users could . . . serve as the basis for determining who is subject to and for the collection of "maintenance fees" for chemicals which continue to be produced/used and as such could provide a portion of the basic resources needed to support EPA's work under the new law. Under such an approach, volume-based fee schedules (e.g., for high/moderate/low volumes (H/M/L)) could be developed for each of the entity groupings throughout the chain of commerce (e.g., manufacturers, processors, users) and be differently applied for each of these H/M/L entity groupings (such as H/M/L manufacturers and importers versus H/M/L processors versus H/M/L users of chemicals). The fees could be levied based on the periodic [CDR] reporting by each entity and be collected at the time of each report.[110]

Other models for identifying and engaging with key members of the regulated supply chain could include the "Preregistration" process established under Europe's Registration, Evaluation and Authorization of Chemicals (REACH) program,[111] the TSCA Reset program proposed by the Administration in 2010,[112] or the rulemaking process to establish a "Candidate List of Active Substances," as proposed in section 8 of the Chemical Safety Improvement Act legislation.[113]

Regardless of the approach taken, stakeholders will need to make tough choices, first in determining how far up or down the supply chain a fee-based structure should extend, and then in designing the logistical and technical procedures necessary to identify, engage, and bill regulated entities.

E. Few Laws Are Perfect From Day 1

Another important take-away is that early iterations of important laws are rarely perfect, and periodic amendment and revision is a normal component of the legislative and environmental policy process. Federal drug and pesticide

107. *Id.*
108. U.S. EPA, FY 2011/2014 OPP Budget Update, Marty Monell, OPP Deputy Office Director 4-5 (Dec. 5, 2013), *available at* http://www.epa.gov/pesticides/ppdc/2013/december/session1-budget.pdf.
109. *See* Charles Auer, *Periodic Reporting of Hazard Data, Exposure Information on Existing Chemicals*, Daily Env't Rep. (BNA), 70 DEN B-1 (04/14/2010), 7.
110. *Id.*
111. *See, e.g.*, ECHA, *REACH Pre-Registration & Registration—Questions and Answers*, MEMO/08/240 (Apr. 4, 2008).
112. *See* U.S. EPA, *Background Discussion Piece: EPA's TSCA Inventory Reset* (Nov. 25, 2008).
113. *See* §8 of S. 1001, Chemical Safety Improvement Act of 2013, *available at* http://www.gpo.gov/fdsys/pkg/BILLS-113s1009is/pdf/BILLS-113s1009is.pdf.

Copyright © 2014 Environmental Law Institute®, Washington, DC. Reprinted with permission from ELR®, http://www.eli.org, 1-800-433-5120.

laws have evolved considerably since their initial introduction early in the 20th century, and Congress, working with EPA and the FDA, went through periods of significant struggle while building, revising, and adapting the legislative, regulatory, and financing structures needed to meet the demands and expectations of their public stakeholders under these statutes. While both continue to be works in progress, both have improved over time and are, for the most part, considered reliable, if not best-in-class regulatory models for their regulated industries.

Compared with the nation's longer history of federal pesticide and drug regulation, the nation's 37-year experiment with federal regulation of chemical substances under TSCA has been relatively short, particularly given the limited opportunity for legislative development and maturation. TSCA is long overdue for a careful review, and recent current bipartisan discussions suggest that Congress may be ready to initiate that process. If so, the growing pains and lessons learned through the development of federal pesticide and drug policy can be instructive, particularly with respect to the importance of providing resources commensurate with the tasks at hand.