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To Test or Not to Test: Tools, Rules, and Corporate Data in US Chemicals Regulation

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Abstract

When the Toxic Substances Control Act (TSCA) was passed by the US Congress in 1976, its advocates pointed to new generation of genotoxicity tests as a way to systematically screen chemicals for carcinogenicity. However, in the end, TSCA did not require any new testing of commercial chemicals, including these rapid laboratory screens. In addition, although the Environmental Protection Agency was to make public data about the health effects of industrial chemicals, companies routinely used the agency's obligation to protect confidential business information to prevent such disclosures. This paper traces the contested history of TSCA and its provisions for testing, from the circulation of the first draft bill in the Nixon administration through the debates over its implementation, which stretched into the Reagan administration. The paucity of publicly available health and environmental data concerning chemicals, I argue, was a by-product of the law and its execution, leading to a situation of institutionalized ignorance, the underside of regulatory knowledge.

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> Before I became interested in chemicals regulation, I had assumed a number of things about the way I imagined the law worked: as a consumer (even, dare to say, an educated consumer), I had placed faith in what I had expected to be fundamental cornerstones for chemicals regulation. The first was that *someone somewhere would regularly be testing chemicals to see if they were harmful*. A second was that, where chemicals were identified as harmful, they would be removed from the market. A third was that manufacturers would know what chemicals went into their products. In TSCA, and as shown in this book, we see that each of these tenets is simply untrue.
>
> —Vaughan (2012, 582 emphases added)

Introduction

Health and safety regulations rely on agreed-upon methods of identifying hazards and assessing risk, often in the absence of good data on human exposure and harm. Standardized tests thus occupy a central place in regulatory science. This paper examines legal requirements for the testing of chemicals as they were specified in the Toxic Substances Control Act (TSCA) signed into US law in 1976.[1] During that decade, scientists introduced a variety of new laboratory-based tools for evaluating genotoxicity (Frickel 2004). For example, bacteria or cultured mammalian cells could be used in vitro to identify those chemicals that mutated DNA or chromosomes, and so could lead to gene damage, birth defects, and cancer. Because such tests were so much quicker and cheaper than rodent carcinogenicity assays, they were already being employed widely in the industry (Kolata 1976; Creager 2014). They were developed as part of a shift toward evaluating low-dose and long-term exposures, expanding the regulatory purview to include chronic as well as acute toxicity (Brickman, Jasanoff, and Ilgen 1985; Vogel 2013; Boudia and Jas 2013, 2014). However, the version of TSCA signed into law did not require manufacturers to provide any toxicity data for chemicals already on the market (Silbergeld, Mandrioli, and Cranor 2015; Cranor 2017). Even the premanufacture notices for *new* chemicals, required by law, did not usually include such results.

Scholars critical of the current state of chemicals regulation point to the lack of testing (Cranor 2011). This paper reconstructs how the absence of

toxicity data for most commercial chemicals arose *in response to* regulation despite the new availability of inexpensive, validated test methods. As legal scholar Lyndon (1989) has observed about US chemicals regulation, "ignorance of toxicity may be an advantage to a product" (p. 1814). This study adds to the robust science and technology studies literature on ignorance, illustrating how the law can become implicated in undone or unseen science (Proctor and Schiebinger 2008; Frickel et al. 2010; Richter, Cordner, and Brown 2018).

Beyond the mere existence of regulatory knowledge is the question of who can access it. TSCA responded to demands for greater transparency about toxic hazards by mandating that health and safety data be made available to the public. However, the Environmental Protection Agency (EPA) was also required to protect proprietary business information, and companies routinely invoked confidentiality to prevent toxicity data from being made public. Industry proved able to exploit provisions of the law to prevent both submission and publication of health and safety data for chemicals.

That TSCA should result in *limiting* regulatory knowledge was, to most observers, a counterintuitive outcome, one that resulted from ongoing legal maneuvering over the law's requirements among politicians, industry representatives, agency officials, and environmental groups. It may not be surprising to find that the chemical sector prevailed, allowing the continuation of unknown toxic exposures from their products. In most cases, this stemmed not from risk assessment but from avoidance of identifying hazards, the first step of that process (Demortain 2019). In response to government's limited action, environmental activists countered with right-to-know initiatives and by mobilizing lay expertise (Fortun 2004, 2009; Ottinger and Cohen 2011). But for most of the 85,000 chemicals now on the market, toxicity data remain unavailable. This paper shows how the making and management of a key law led to institutionalized ignorance, the underside of regulatory knowledge (Jasanoff 1990; Frickel and Edwards 2014).[2]

Environmental Carcinogens as a Political Matter in the 1960s–1970s

In 1962, Rachel Carson's *Silent Spring* focused concern on the dangers of agents such as dichlorodiphenyltrichloroethane (DDT) and synthetic chemicals in industrial pollution—hazards to both human health and wildlife. Historians have documented how the influence of this one book drew on

many other developments and public movements such as the debates over radioactive fallout from atomic weapons testing, the loss of native plants and animals in association with suburbanization and pollution, worries about carcinogenic food additives, and the fouling of rivers and landscapes with noxious industrial waste (Whorton 1974; Lutts 1985; Hays 1987; Sellers 2012). Carson's book, in other words, was the crest of a wave that had been building for some time and which gained strength in the 1960s.

Scientists, physicians, and activists focused particular attention on the role of food additives, pesticides, and pollution in human cancer. By the late 1960s, the US federal government targeted cancer from chemicals as a key public health problem. In 1968, the National Cancer Institute launched a "Plan for Chemical Carcinogenesis and the Prevention of Cancers." During the subsequent years, the agency publicized an estimate that as much as 90 percent of human cancer was due to environmental agents, which most understood to be synthetic chemicals (Boyland 1967; Higginson 1969). As National Institutes of Health director Robert S. Stone declared, "Most known environmental carcinogens are a result of our increased agricultural and industrial technology" (US Congress Senate 1975, 255). However, there was not a unified system for identifying or regulating environmental carcinogens, and US voters and public interest groups began demanding better oversight.

In response, the US Congress passed the National Environmental Policy Act (NEPA) in 1969 and, one year later, the Environmental Quality Improvement Act. NEPA provided the president with an independent advisory board, the Council on Environmental Quality (CEQ). Russell E. Train became chair of the CEQ, the only federal entity with "environment" in its name on the first Earth Day (April 22, 1970; Davies 2009). The council advocated for more effective policies concerning pollution control and land use. In part through the influence of Train, the Nixon administration supported the Clean Air Act of 1970. Industry, however, gained an administrative foothold when the president established a National Industrial Pollution Control Council in the Department of Commerce. This Council was composed of the top corporate executives, and its creation signaled coming opposition within the administration to any new environmental legislation. For example, the Clean Water Act of 1972 was passed by Congress by a two-thirds majority, after being vetoed by the president (Hays 1987, 58).

In 1970, Nixon issued an executive order that consolidated federal oversight over pollution in the new US EPA. The founding of the EPA is generally cited as a major advance in environmental regulation, but

there is no single piece of legislation that sets forth its mission. Instead, it oversees the implementation of many distinct laws passed at various times for different reasons (Mazurek and Davies 1998, 16). One expectation for the agency was that it would institute more comprehensive regulation of polluting chemicals. The Clean Water Act and the Clean Air Act set out specific goals for contaminants in these two media (water and air), but existing regulation of terrestrial chemicals, whether indoor or outdoor, remained highly fragmented. Exposures in the workplace had long been managed through private industry standards and, after 1971, also by the US Occupational Safety and Health Administration (Corn 1989). Pesticides were registered under the Federal Insecticides, Fungicides, and Rodenticides Act (FIFRA), whose implementation the EPA took over from the US Department of Agriculture.[3] Safety of food additives and preservatives, as well as drugs, was overseen by the Food and Drug Administration (FDA). Radioactive materials fell under the purview of the Atomic Energy Commission and, after 1974, the Nuclear Regulatory Commission. In 1972, the Consumer Product Safety Commission established safety standards and, when needed, mandated recalls for around 15,000 consumer products. Each of these agencies had its own priorities and scientific standards for safety. Chemicals not falling under any of these frameworks were largely unregulated by the federal government.

Debating a Toxic Substances Control Act, 1971–1975

The CEQ argued for more comprehensive oversight of chemicals, particularly through its report "Toxic Substances" (CEQ 1971b). Staff member J. Clarence Davies, a specialist on environmental policy, collaborated with Charles F. Lettow, a Republican lawyer who had also worked as a chemical engineer at Dow Chemicals, to draft a Toxic Substances Control Act (CEQ 1970, 2). Their initial draft, which was circulated to other government agencies in December 1970, outlined a federal program for systematic regulation including the collection of data for toxic substances (CEQ 1972, 20). It was intended to be a "queen statute" pertaining to the entire realm of chemicals, even as it exempted those substances controlled by other laws including FIFRA, the Atomic Energy Act, and The Federal Food, Drug, and Cosmetic Act (CEQ 1971a, 153).

The CEQ's proposed bill authorized the EPA to restrict or otherwise regulate chemical substances that endangered human health or the environment (CEQ 1971a, 148). The bill emphasized substances whose effects—particularly cancer, birth defects, and heritable mutations—resulted from

long-term and chronic exposure and so might be missed in acute toxicity tests. How could these toxic substances be identified for control, given the 60,000 chemicals already on the market, and the 1,000 or so introduced each year? According to the bill, EPA could set up its own laboratories for testing and monitoring, but the burden of testing was not to be placed solely on the government. In this initial draft, the administrator could require companies to report certain data on chemicals already on the market, including chemical identity, molecular structure, amount produced, by-products, and, when requested, health and environmental data (CEQ 1971a, 152). In addition, companies seeking to bring *new* chemicals to market would be required to first show that they met health and environmental test standards specified by the agency (CEQ 1971a, 144).

This premarket requirement was very unpopular with industry, whose interests were represented in the Department of Commerce. In the American system, bills proposed by the Executive Branch are generally vetted with agencies and other stakeholders before being sponsored by the members of the House and Senate who formally submit them for consideration. Thus, before the Nixon administration sent the bill to Congress on February 11, 1971, lawyers in Commerce stripped it of its premanufacture testing requirement (Davies 2009, 10-11). Yet, testing remained a focus of the revised bill—and throughout TSCA's long gestation (Quarles 1976). The law was seen by contemporaries as primarily a mechanism through which the federal government could compel "a manufacturer or processor to test the effect of a substance on health and the environment" (Gaynor 1977, 1180).

TSCA was introduced into the Senate as S. 1478 in June 1971. In July, Senator William B. Spong (D-VA) introduced an amendment that made the testing and reporting requirements more stringent. First, it clarified that for new substances, "testing should be the responsibility of those who produce such chemicals" (US Congress Senate 1972, 31). Second, it required EPA to specify, within a year of the enacted legislation, standard protocols for testing effects such as "carcinogenesis, mutagenesis, persistence, the cumulative or synergistic effects of other chemical substances, and other chemical hazards" (US Congress Senate 1972, 35). In the case of chemicals already on the market, companies would have to report whatever test data they already had. For new chemicals, companies would have to undertake the tests specified by EPA; they were, however, entitled to request reimbursement from the EPA for the costs of required testing paid for through a tax levied on the new chemicals (US Congress Senate 1972, 62). Third, and most importantly, manufacturers would be required to report these test

results to the EPA and *receive agency authorization* before production of any new commercial chemical. In other words, the provision the Department of Commerce had kept out of the CEQ's first version of the bill was back in. The Senate amendment also permitted citizens to take civil action to instigate regulatory action against alleged violations of the act or against the Administrator for not performing his or her duties.

Senate hearings on S. 1478 did not take place until October 1971. The chairman of the CEQ, Russell Train, testified on behalf of the Nixon administration's version of the bill, opposing Spong's amendment. He voiced concern that the premarket clearance provisions of the amendment would impose heavy regulatory burdens on the EPA (US Congress Senate 1972, 67). C. Boyd Shaffer, representing the Manufacturing Chemists Association (the industry trade group), also made a statement opposing the amendment to the bill, claiming that new regulation would "impede innovation" by requiring tests for assessing chronic toxicity, especially carcinogenicity. In particular, as he observed, requiring animal tests could delay a product three to four years and cost US$200,000 (US Congress Senate 1972, 267). He emphasized that no one in the industry objected to doing tests but that the "burden created by the indiscriminate imposition of excessive testing requirements would effectively eliminate the innovative role of the smaller chemical companies" (US Congress Senate 1972, 268). He instead endorsed the original provisions in S. 1478, which made testing essentially voluntary for existing chemicals except for certain classes deemed potentially hazardous.[4]

Divisions over key provisions of the legislation (and likely direct lobbying by industry) delayed a vote. As reported to the chemistry industry in a November 1971 update, "Our Washington sources . . . inform us that the Toxic Substances Control Act (S-1478) will probably be installed in the Senate Commerce Committee for the rest of the Congressional session" (Swetonic 1971). However, the Senate did eventually pass S. 1478, largely as amended by Spong, on May 30, 1972. Then, the House of Representatives took up and passed their version of the bill on October 30 (H. R. 5276). The House version was essentially the Nixon administration's bill. It did not include the Senate version's more stringent requirements for premarket testing and authorization of new chemicals. The bill died in the Senate–House Conference Committee during the ninety-second session of Congress (EPA 1997, 107; Nemkov 1972).

According to J. Clarence Davies, the unified approach to chemicals regulation, intended to give the law comprehensive reach, proved to be a political liability. Conventional environmental legislation focused on a

specific media: air, land, and water (McCubbins, Noll, and Weingast 1987). Environmental and conservation groups preferred to work with federal agencies that had traditionally had oversight of these different geographical aspects of protection (Davies 2009, 13). Needless to say, as the Watergate scandal escalated in 1973, Congress was becoming consumed by other matters. Nixon resigned on August 9, 1974. During this period, the House and Senate of the ninety-third Congress again passed different versions of TSCA, and the legislation died in committee. It did not help that President Ford first supported and then opposed the premarket authorization provision that had been so divisive (EPA 1997, 107).

A Law Industry Can Live with

In July 1975, a scandal reignited political pressure for chemicals regulation. Dozens of workers at a chemical factory in Virginia were poisoned through their exposure to Kepone, a neurotoxic pesticide manufactured in the plant (Reich and Spong 1983). Committees in the ninety-fourth Congress took up TSCA again, holding hearings throughout 1975. Supporters of TSCA now pointed to the generation of new short-term bioassays for carcinogenicity that might be used in screening substances. As a Congressional report on the legislation noted, "Illustrative is the salmonella test developed by Dr. Bruce Ames of the University of California, Berkeley, which is now available for screening for cancer-causing properties of chemicals and which has considerably reduced both the costs and the time required for such screening" (Library of Congress 1976, 413). The existence of these new assays, especially this one referred to as the "Ames test," spurred a lively debate over whether animal testing was still necessary (Library of Congress 1976, 562-63). In any case, such new tests meant that initial screening of all chemicals for long-term effects was now feasible.

The administration made it clear that some version of TSCA needed to pass to appease political pressure, so a group of industry players began hammering out the details with Congress (EPA 1997, 107). Key concessions to industry revolved around testing—whether it would be required, who would conduct it, and whether test results would have to be disclosed. The agreed-upon bill was passed by Congress on September 28, 1976, and was signed into law by President Ford on October 11, 1976.

The final statute created many procedural hurdles for EPA in fulfilling its mandate to regulate chemicals. These hurdles were not an oversight but compromises made with the Manufacturing Chemists Association to produce a bill acceptable to this trade group. O'Reilly (2010), an industry

lawyer who actually helped write the provisions, has said: "The 1976 Toxic Substances Control Act (TSCA) contains such obscure and inconsistent phrases that its supporters were doomed to frustration" (p. 43). He refers to TSCA as "a failed statute" and to interpreting the bill as "torture." Legal scholar Kevin Gaynor (1977), who analyzed the law shortly after it passed, called it "a regulatory morass." Even its provisions "ensuring transparency of safety data" became "rigid procedural handcuffs" (O'Reilly, 2010, 43). This was a statute designed to make the oversight of industry difficult.

The antiregulatory policies and conservative political appointments of the Reagan administration further consolidated the trajectory of TSCA as a regulatory failure. Over the course of the 1980s, the judiciary set a high bar for what constituted "unreasonable risk," which involved subjecting the control of health and environmental exposures to cost-benefit analysis. In part because the benefits of nonexposure are hard to quantify, it was (and remains) exceedingly difficult for the EPA to demonstrate that the benefits of removing a risk outweigh the easier-to-tabulate economic costs. The legal challenges faced by EPA were demonstrated most spectacularly by the fate of its 1989 Asbestos Ban and Phase-Out Rule, which aimed to get most asbestos-containing products off the market. Industry successfully contested the rule, which was invalidated in 1991 by the US Court of Appeals, a decision the head of the EPA declined to appeal (Stadler 1993).

The Implementation of TSCA

TSCA authorized EPA to review both existing chemicals (the roughly 60,000 already on the market) and new commercial chemicals (maybe 1,000 per year), but the regulatory processes were completely different. For *existing* chemicals, the EPA was responsible for regulating those that posed "unreasonable risk" to human health or the environment. Industry was required to report all chemicals to be manufactured. The EPA could require companies to test their chemicals for health and environmental effects and submit the data. But in order to either (1) require new testing or (2) obtain existing data on a chemical of concern from the manufacturer, the EPA had to issue a rule.[5] In most cases, TSCA required the agency to determine that current data were inadequate, testing was necessary, and the chemical posed an "unreasonable risk." As Lyndon (2012) puts it, this "creates a Catch-22 situation, in which the EPA must prove that a chemical is likely to be harmful before it can require testing" (p. 461). Just as significantly, the process of rulemaking under the Administrative Procedure Act was cumbersome, including mechanisms for providing public and industry input,

through a hearing or comment period (Grisinger 2012). Consequently, a rule could take months or even years to issue, with the process costing the agency hundreds of thousands of dollars (US General Accounting Office [GAO] 2009, 5-6). Not surprisingly, from 1976 through 2009, the EPA issued rules requiring testing on only 200 chemicals on the market.[6] For the most part, existing chemicals, once inventoried, were left alone.

TSCA's regulations for *new* chemicals required companies to file notices with the agency at least ninety days ahead of manufacture, enabling EPA review and possible action. According to an EPA (1997) history of the bill, "Chemical industry representatives expressed afterwards that they had agreed to premanufacture notification (which had remained in the final bill) in exchange for reduced reporting provisions" (p. 107). The critical issue, from the industry's point of view, was *what* exactly would be required in a premanufacture notification (PMN). One industry scientist observed that it was to "contain adequate manufacturing, use, and biological information on the new chemical to permit hazard evaluation by the EPA" (Jaeschke 1978, 15). In the absence of such data, and if there was an indication of "unreasonable risk to health and the environment," the EPA could extend the review period, require the manufacturer to submit further information, put restrictions on the nature of product use, or prevent that chemical coming to market in the United States. But enforcement of the test data requirement relied on the EPA issuing an order.[7] If the EPA took no action on a PMN, the manufacturer would report to the agency when it began production (a "notice of commencement"), and the chemical would be added to the agency's inventory of commercial chemicals.

TSCA includes many passages about testing and reporting, with stipulations and exemptions hard to untangle. As one Environmental Defense Fund lawyer commented, "many of EPA's difficulties in implementing the Toxic Substances Control Act can be traced to seemingly competing considerations which are built into the law, in recognition of the widely differing interests involved" (US Congress House of Representatives 1979, 14). Nowhere were the challenges of translating "the legislative mandate of the Toxic Substances Control Act into a regulatory reality" more evident than in specifying the process for filing PMN's (US Congress House of Representatives 1979, 152). On January 10, 1979, the EPA published its proposal and draft PMN form in the *Federal Register* (EPA 1979). While laying out several alternative possibilities for the submission requirements for a new chemical, EPA made clear its preference for determining the specific tests for which a company would be required to submit data on a case-by-case basis, taking into account the chemical's structure, properties, uses,

exposures, and so on (EPA 1979, 2260). The EPA also proposed a rule allowing the agency to invalidate any PMN that did not include all required information.

Industry was not happy with EPA's proposal for PMNs. In TSCA oversight hearings in March 1979, several executives expressed their concerns. Etcyl H. Blair of Dow Chemical Corporation testified on behalf of the Manufacturing Chemists Association. He argued that the EPA's ability to invalidate a PMN form, because it either did not comply with requirements or lacked certain data, would threaten innovation in the chemical industry. "We want the invalidation concept completely removed" (US Congress House of Representatives 1979, 33). He also objected to "just too much data being requested on that form" and argued EPA should not be able to specify the required tests. As Blair noted, "Nowhere in the Act does it state that [the manufacturer] will perform certain tests" (US Congress House of Representatives 1979, 33-34). For new chemicals, unless the EPA had issued a test rule on the new chemical or its class of chemicals, filing a PMN did not require a manufacturer to conduct any new testing of health and environmental effects (Library of Congress 1976, 6). Under the Reagan administration, the EPA (1982) abandoned any effort to standardize submitted data, admitting that their published test protocols were to serve as "informal guidelines rather than as generic methodology requirements" (p. 6).

There was a proviso: the law stipulates that *if* the applicant possessed any such data, it had to be submitted as part of the PMN. Each PMN was to include "a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable."[8] The EPA's forms made clear that this included data in the possession of the company as well as in the published literature. Any submitted data would, of course, be taken into account by the EPA in their hazard evaluation (the first step in formal risk assessment). Companies were loath to supply any sort of health and safety data that could trigger agency review. The result, intended or not, was that the TSCA created a powerful disincentive among manufacturers to undertake toxicity testing of new chemicals, including inexpensive mutagenicity testing (Wagner 2004), or to report what they had. As Lyndon (2012) has commented, "This duty to reveal existing data is difficult to enforce and has often been ignored" (p. 461).

This outcome was not obvious to all observers at the time. Until TSCA was actually implemented, it appeared that the law would be precautionary enough that a short-term mutagenicity assay could serve as a kind of screen

the EPA could use to require further testing, either for existing chemicals or for new chemicals. As *Environmental Law Reporter* observed a month after the bill was signed into law, "in many cases the manufacturer will submit Ames assay results with the premarket notification" ("From Microbes to Men" 1976, 10252). This expectation was built on the fact, as reported by science writer Gina Kolata (1976) in *Science* magazine the year before, that the chemical industry was already routinely applying this test on its potential products.[9] Private testing labs such as Litton-Bionetics and companies, including Monsanto and Allied Chemicals, had expanded their laboratory capacity for testing, anticipating a dramatic increase in the testing of chemicals. This did not materialize (Lyndon 1989, 1822 n102). Legal scholar Kevin Gaynor noted in 1977 that for companies, TSCA disincentivized doing even a simple mutagenicity test:

> A testing rule must be issued if a substance "may present" an unreasonable risk while a substantive regulation may be issued only if there is a "reasonable basis to conclude" that the substance "will present or presents" an unreasonable risk . . . . The "may present" requirement, coupled with the minimal losses [to calculated benefits in a risk assessment] caused by a testing rule, creates a standard so low that a positive result in a simple Ames [mutagenicity] test might trigger [more costly] testing. (p. 1154)

In the end, remarkably few PMNs submitted to the EPA included the expected health and environmental testing data. The paucity of such data came up in 1983 Senate hearings regarding TSCA Oversight. As Michael Gough of the Office of Technology Assessment explained the situation,

> TSCA singled out chemicals that may cause cancer, mutations, or birth defects, the so-called chronic health effects, for special concern. Tests for the capacity to cause cancer or birth defects are expensive and time-consuming, and only tests for mutagenicity can be expected to be carried out on chemicals before manufacture. (US Congress Senate 1984, 146)[10]

However, as he continued, only "17 percent of PMN's reported mutagenicity data." And most PMN's contained "no toxicity information" (US Congress Senate 1984, 147). When such information was included at all, it was more likely to be acute toxicity data (e.g., skin irritation test) rather than assays for the effects of chronic health exposures, the ones that TSCA had been designed to address. In contrast to the absence of health and environmental data, over 90 percent of PMNs included required data on the identity

of the chemical, projected production volume, likely uses, anticipated worker exposures, and disposal methods.[11] Asked by Senator Durenberger if the missing toxicity data were a matter of cost, Gough responded, "The simplest test, which is a test for the capacity to cause mutations in bacteria, is not expensive, on the order of US$1,000 to US$2,000. I don't think cost is the reason" (US Congress Senate 1984, 147). Later in the same hearing, a representative from Union Carbide Corporation claimed that "companies are doing more testing and they are watching their research projects more carefully with respect to the toxicology of things" (US Congress Senate 1984, 160). That assertion makes the lack of submitted test results in PMNs even more perplexing. In the absence of test data for new chemicals, the EPA based most of its decisions about requiring further testing or restricting uses for new chemicals on structure–activity relationships, a model-based prediction method (Boullier, Demortain, and Zeeman 2019).

Data Drought

Industry's (un)willingness to share information affected EPA's ability to fulfill two of its responsibilities under TSCA. First, the new law required the agency to enumerate, within a year, all existing commercial chemicals in the TSCA Chemical Substance Inventory. This mandate made the centralization of information a necessary first step to any regulatory action, including of new chemicals. For a company wishing to produce a new chemical, the first step in complying with TSCA was to check whether the substance to be manufactured was already on the Inventory of existing chemicals. If it was, no PMN was required. If it wasn't, a PMN was required. If the EPA took no action in response to the company's PMN, and production commenced, that new chemical was added to the Inventory, joining the ranks of existing chemicals.

It proved impossible for the EPA to create the TSCA Inventory by Congress's deadline.[12] To start with, coming up with a unified organizational scheme for chemicals was an enormous technical challenge. There existed many databases of toxic chemicals already, whose classification schemes were not compatible (Jas 2014). The EPA decided to use the organization of chemical substances developed by Chemical Abstracts Service (CAS), which began as an American periodical index before developing into a registry of all known chemical compounds. EPA contracted with CAS to maintain the TSCA Inventory, which was organized around a structural formula for each item and a unique registry number. This system was an enumeration, not a classification; it did not make visible the

relationships (structural and otherwise) between different chemicals (Hepler-Smith 2019).

To fulfill its regulatory mandate for existing chemicals in the inventory, the EPA needed to gather other scientific information (than structural formula) about commercial chemicals, such as physical and chemical characteristics and toxicity as determined by standard tests. The agency assumed that the industry possessed and would provide the requisite data on commercial chemicals. This approach had worked in the regulation of pesticides and herbicides on the one hand and drugs on the other, for which industry was required to provide data in order for products to be authorized—and did so. But in the case of commercial chemicals, the industry was not interested in sharing data, and EPA lacked the infrastructure or resources to generate its own. As Boyd (2017) has put it, "Although TSCA was supposed to be an information-forcing statute, in many respects it had the opposite effect. Industry had no incentive to generate any new information under the statute; in fact, it had every incentive not to do so" (p. 22).

Second, problems with data gathering affected EPA's responsibility to inform consumers about the chemicals to which they were exposed. TSCA specified that health effects data received in premanufacture notices were supposed to be released to the general public along with the chemical identity of the substance (Gaynor 1977, 1645). However, this mandate came into conflict with the EPA's responsibility to protect confidential business information, which was claimed by companies in the vast majority of the submitted PMNs (US GAO 1994, 5). To protect proprietary information, the agency resorted to using generic names for chemicals, making the published health and safety data of little use.[13] In addition, the publicly accessible TSCA Inventory of Chemical Substances noted substances for which further testing was required (e.g., 5(e) orders) or whose restrictions were limited to avoid exposure (e.g., 5(f) rules). But this did not make the relevant health and safety data available to the public (US Congress House of Representatives 1979, 194).[14] In 1997, the Environmental Defense Fund (1997) reported that for the top-selling 3,000 chemicals in the United States, basic toxicity testing was unavailable to the public for more than 70 percent. Skeptical government officials and industry undertook their own assessments and found that the Environmental Defense Fund had underestimated the magnitude of the problem: according to the EPA and the Chemical Manufacturers Association, more than 90 percent of high-production chemicals lacked publicly available health data (EPA 1998; Denison 2004). A joint government–industry program to make this information available was launched but never completed. Whether the absence of data is because

scientific studies have not been done or have not been shared cannot be easily discerned, but in either case, companies can usually claim to be in compliance with TSCA (Frickel et al. 2010; for an important example of documented non-compliance, Richter, Cordner, and Brown 2018).

Conclusions

When President Ford signed the TSCA, he declared, "Through the testing and reporting requirements of the law, our understanding of these [tens of thousands of commercial] chemicals should be greatly enhanced" (Library of Congress 1976, 53). As this paper has shown, TSCA had the opposite effect. Importantly, and unlike in the 1960s, the problem was not that testing technologies were too lengthy and expensive. The development of the low-cost, rapid mutagenicity tests in the 1970s made feasible the screening of all commercial chemicals to identify those that might be associated with long-term hazards, notably carcinogenicity. Even economists pointed to the desirability of screening at least all new chemicals for mutagenicity; such an effort would cost only "a tiny fraction of what researchers at the National Institutes of Health spend chasing apparently nonexisting [cancer-causing] viruses" (Kneese and Schulze 1977, 328).[15] EPA officials did not believe a positive mutagenicity test would necessarily kill a promising chemical. As Jellinek (2010) recalls from his vantage point as EPA's assistant administrator for pesticides and toxic substances, "[A] positive mutagenicity test, you know [is] an indication there may be an issue, but nobody's going to walk away from a major existing chemical because of that" (p. 16). Yet in the United States, the enactment of TSCA effectively thwarted the prospect of requiring that all commercial chemicals be screened for mutagenicity or any other health effect.

This lack of testing was specific to the commercial chemicals sector. For pharmaceuticals as regulated by the FDA, the burden of proof is on industry to demonstrate the safety and efficacy of new products. Industry scientists have told me that genotoxicity (e.g., mutagenicity) testing was and is used routinely, even universally, in drug development. In general, substances testing positive are excluded from further product development. (An exception is usually made for chemotherapeutic agents; for many, genotoxicity is the key to their mechanism, and their benefits for cancer patients usually outweigh the risks.) Such routine screening has clearly shaped the pharmaceuticals that are on the market. One paper cites a study showing that fewer marketed drugs test positively for mutagenicity than commercial chemicals (7 percent compared with 20 percent); the authors attribute this to extensive

early screening to eliminate mutagenic compounds (Claxton, Umbuzeiro, and DeMarini 2010, 1518). For its part, the FDA issues guidelines for mutagenicity testing and regularly reviews such data as part of the registration of pharmaceuticals, for which comprehensive assessment of genotoxicity is required.[16]

In the end, the fact that commercial chemicals in the United States are not widely screened for health and environmental effects was bound up with the passage and implementation of TSCA. As in the homophonous opera, Tosca, torture was followed by an unhappy ending. By the 2000s, even the chemical sector was sufficiently frustrated with TSCA to advocate for its reform. One advantage industry can gain from regulatory oversight is public trust, but TSCA failed to generate consumer faith in commercial chemicals. In addition, American chemicals regulation was out of step with other national and international directives, especially that adopted by the European Union (US GAO 2007). On June 22, 2016, the Frank R. Lautenberg Chemical Safety Act for the twenty-first Century amended TSCA to begin requiring more toxicity data on high-volume chemicals (Krimsky 2017). Months later, the election of Donald Trump to the White House radically changed EPA's priorities. It remains to be seen whether the revamped TSCA will augment chemicals testing and data sharing to overcome a legacy of ignorance about toxic exposures.

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Notes

1. For comparative and international chemicals control, see Brickman, Ilgen, and Jasanoff (1985); Pallemaerts (2003); and Lanier-Christensen (this issue).
2. Toxic Substances Control Act (TSCA)'s recent reform has not changed this situation; see the Conclusion.
3. Moving pesticide oversight to Environmental Protection Agency (EPA) from the US Department of Agriculture removed a clear conflict of interest in the regulation of agricultural chemicals (Wellford 1972, 149, 151).
4. As Shaffer claimed, "Voluntary testing by manufacturers has been substantial for many years, and may be expected to continue its present rapid of growth" (US Congress Senate 1972, 268).
5. Provisions enabling EPA to issue these rules originate in different sections of the bill: rules to require testing to be performed and reported would be issued under 15 U.S.C. § 2603 (1982). Rules to require companies to submit test data they already possessed would be issued under 15 U.S.C. § 2607 (1982).
6. §4e of TSCA established an Inter-Agency Testing Committee to identify existing chemicals of greatest concern.
7. In this case, a 5(e) order, which is less procedurally burdensome than a rule.
8. Toxic Substances Control Act, 15 U.S.C. § 2604 (1982), 1123.
9. "This has led to a curious situation in which industries are implicitly endorsing the tests at the same time that scientists and legislators deliberate over whether companies should be forced to use them" (Kolata 1976, 1215).
10. In his statement to Congress, Gough was drawing on a report from his agency (Office of Technology Assessment 1983). As he indicates later, he and J. Stedman Stevens wrote that report (US Congress Senate 1984, 189).
11. As Gough points out, this statistic "means that not all PMN's report even the TSCA-specified items" (US Congress Senate 1984, 146).
12. The TSCA inventory finally appeared on June 30, 1979 (Office of Technology Assessment 1983, 12).
13. For a real-time synopsis of this conundrum, see "US Toxic Substances Control Act, Addendum to Record of 14th (special) Meeting, 14–16 June 1977," in ENV/CHEM(77), OECD Archives, Paris.
14. However, EPA has taken steps in this direction with Toxic Substances Control Act Submissions (TSCATS) and ChemView.
15. They were presumably referring to the massively funded efforts, as part of Nixon's War on Cancer, to identify cancer viruses (see Wade 1971; Scheffler 2019).

16. For example, "Guidance for Industry: S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use," https://www.fda.gov/downloads/drugs/guidances/ucm074931.pdf.

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