

The Real Meaning of "TSCA Modernization"

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Standards to Over-Precaution

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MARCH 2012



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Executive Summary

Republicans, Democrats, industry representatives, and environmentalists all say they agree that it is time to “modernize” the Toxic Substances Control Act (TSCA—pronounced “tosca”), the federal law that regulates chemicals not covered under other federal laws. Some say the law needs an overhaul because it is too weak and has accomplished little, while others maintain that modest changes to facilitate greater data collection and chemical testing by the U.S. Environmental Protection Agency (EPA) could improve implementation. Both views suggest that reforms should grant the EPA greater powers to advance public health.

In reality, changes to TSCA are highly unlikely to have any measurable positive effect on public health, given the scant evidence that the trace-level chemicals that TSCA regulates have any significant health impacts. Rather, a stronger TSCA law may harm human well being by leading to bans on many valuable products, undermining innovation, and diverting resources from valuable enterprises to meet burdensome regulatory mandates.

TSCA’s one commendable attribute is that it imposes a reasonable risk-based standard, one that applies many regulatory accountability standards, including some covered in President Obama’s executive order on regulatory reform. It allows the EPA to regulate when a chemical poses an “unreasonable risk of injury to health or the environment.” If the EPA finds that a chemical does in fact pose such an unreasonable risk, it may prohibit its use, impose regulations limiting its use, mandate recordkeeping, set disposal regulations, require posted warnings related to its use, and other requirements. It states further that the agency must apply such restrictions “to the extent necessary to protect adequately against such risk using the least burdensome requirements.”

This is a rational and solid risk-based standard that is unique within U.S. environmental law. It directs the EPA to focus on scientifically robust, well-designed studies. It also demands that the agency consider both cost-benefit considerations and potentially adverse outcomes of its regulatory actions. Citizens should demand at least as much before any governmental body issues regulations that undermine the freedoms necessary for society to progress and innovate.

Yet TSCA reform proposals all strike at the heart of this standard, calling instead for a hazard-based, precautionary approach. Some would model the new rule after the “reasonable certainty of no harm” standard set in the Food Quality Protection Act, which has produced a host of unnecessary bans and regulations on valuable products that are used to help ensure affordable food production and control of dangerous pests.

Additional data mandates under TSCA are also unnecessary and dangerous. Contrary to many claims, the EPA has managed to use the law to impose thousands of regulations, collect substantial data under both mandatory and voluntary programs, and demand testing of chemicals. Still, the EPA and environmentalists would like greater power to collect “new” data on a number of chemicals that have already been studied

extensively by private companies, government agencies, and research bodies around the world. The EPA is unlikely to discover damning information regarding chemicals that have been used for decades without indication of adverse health concerns. Instead, mandates for additional study will simply divert research dollars away from more valuable research and development efforts.

TSCA's actual failures stem from cases where the EPA has succeeded in taking regulatory actions under the law. The agency has been able to use the law to impose some needless regulations related to lead-based paint, polychlorinated biphenyls, dioxin, and other substances. Obama administration efforts to revitalize the law indicate that the EPA can use the law to impose a host of new regulations as well as make symbolic statements about chemicals to adversely impact their use in the U.S. marketplace—even without congressional authorization.

“Modernization” will most likely empower the agency to take these programs in an even more arbitrary and capricious direction, undermining freedom, innovation, and economic growth in exchange for no measurable public health benefits.

Introduction

Republicans, Democrats, industry representatives, and environmentalists all say they agree that it is time to “modernize” the Toxic Substances Control Act (TSCA—pronounced “tos-ca”), the federal law that regulates chemicals not covered under other federal laws. Some modernization advocates maintain that the law does not allow the U.S. Environmental Protection Agency (EPA) to collect enough data to study chemicals to determine risks.¹ Environmental activists charge further that the law’s existing risk standard prevents the agency from protecting public health by imposing chemical bans and regulations.² At the same time, the Obama administration has initiated a host of new TSCA regulatory initiatives, while advocating legislative reforms that would strengthen its ability to impose more stringent TSCA regulations.

This paper assesses the concerns regarding TSCA’s alleged failures by examining its statutory outline and implementation during the past several decades. It demonstrates that, despite claims to the contrary, strengthening the law is not necessary to protect public health. TSCA’s “failure” to impose more extensive regulation results from the law’s reasonable risk-based standard, which prevents many unwarranted intrusions into the marketplace. In addition, the EPA manages to collect massive amounts of data, more than it can process into useful information. The notion that collecting more data will improve public health is highly suspect.

TSCA is not without implementation problems, but the source is largely the opposite of what some modernization advocates proclaim. This paper will show how the EPA has managed to use the law to impose some significant and often needless regulations that promise little environmental benefit in exchange for high costs to industry. In addition, the Obama administration’s recent efforts promise more aggressive implementation of the law and are likely to be both costly and unnecessary.

Unfortunately, these problems will not be fixed with the legislative reform proposals currently on the table. Supporters of modernization have indicated the desire to reform TSCA by increasing EPA power either by mandating additional industry data collection and testing programs or by replacing the law’s risk-based standard with a precautionary approach. Many activists and some members of Congress support both changes.

Industry groups largely support TSCA reform for a very practical reason: Their Washington lobbyists maintain that a revised federal toxics law could preempt the dozens of existing and proposed state laws around the nation. After all, it is easier to follow one master than 50. Phil Klein of the Consumer Specialty

The Obama administration’s recent efforts promise more aggressive implementation of the law and are likely to be both costly and unnecessary.

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Products Association (CSPA) explains, “As of today, 30 states have introduced chemical-related legislation. We would like one strong federal standard.”³ CSPA—which represents manufacturers of a host of consumer products, from cleaning detergents to bug spray—is part of a larger, industry coalition led by the American Chemistry Council that is pushing for TSCA reform with the hopes of gaining preemption.

However, there are very few instances in which federal environmental laws preempt state law. In fact, it almost never happens. Instead, federal laws provide the floor—allowing states to impose more onerous standards in addition to federal standards. TSCA reform bills during the 111th Congress excluded preemption because of strong opposition from environmentalists and state-level policy makers.

Some Republicans support reform based on the idea that it could promote reasonable, science-based standards with minimal economic impacts. In a statement submitted at a congressional hearing, Sen. James Inhofe (R-Okla.) explained, “[W]e can reach an agreement to develop a workable bill, one based on the best available science, one that protects human health, and one that balances the need to protect jobs and economic growth.”⁴

Ironically, TSCA already embodies much of these elements and others advocated by reform advocates on the right. As it exists today, TSCA requires validated scientific justifications for regulation, cost-benefit considerations, weighing of risks associated with both the chemical regulated and the potential regulation itself, as well as consideration of adverse economic impacts. Rather than call for modernization, supporters of such common sense regulatory reform should hold TSCA up as an example of successful implementation of such standards.

Calls for TSCA “modernization” move the debate in the opposite direction. In fact, the impetus for TSCA reform comes from the desire of left-leaning self-styled “public health” advocates to depart from hard science and cost-benefit considerations in favor of more precautionary policies. Environmentalists and Democrats want to replace TSCA’s science-based standard with a political one based on the precautionary principle—a concept that calls on regulators to act even in the absence of scientific justifications. For example, Richard Dennison of the Environmental Defense Fund advocates a “presumed guilty until proven innocent” approach for TSCA reform.⁵ Sen. Frank Lautenberg (D-N.J.) noted back in 2009 that the goal of his legislation is to “put the burden of proving chemical safety where it belongs: on chemical companies.”⁶

Shift from Risk-Based Policies to Precaution

A review of some key regulatory trends demonstrates that “modernization” entails the shift away from risk-based standards to standards based on the precautionary principle. This principle is a regulatory concept designed to appeal to a natural desire for security and safety, something which the public health portfolio of environmental issues promises to deliver. When people hear of the concept, it appears to be a common-sense policy of “better safe than sorry.”

Opposing the principle is politically difficult, as it makes policy makers appear callous and uncaring, even though the principle is technically impossible to meet. Once the precautionary principle is accepted as a matter of policy, it presses policy makers to make regulations as stringent as possible and even encourages lawmakers to ban certain technologies on the basis that they *might* pose safety risks. In essence, it grants regulators arbitrary power to regulate based on political rather than scientific or risk-based grounds.

The precautionary principle shifts regulation away from risk-based standards toward hazard-based ones. Risk standards require policy makers to determine an acceptable risk level for society, ideally based on the best available, peer-reviewed science and a solid understanding of human exposure to the chemical. Often determinations include weighing those estimated risks against expected benefits that the substance may bring.

Hazard-based standards only consider whether something has the *potential* for harm at some level. A chemical may be dubbed “hazardous,” even if it poses little risk at existing exposure levels. For example, water can be considered hazardous because excessive consumption can produce fatal “water intoxication.”⁷

Hazard alone is not a good justification for regulation, yet advocates of precaution suggest it should be. Moreover, a hazard assessment is usually only one step in the risk assessment process, whereby researchers consider risks associated with actual or estimated exposures.

It is worth noting, however, that even risk-based regulation can prove excessively precautionary. In fact, most of the highly precautionary laws and regulations currently on the books include some form of risk assessment. That is because regulators tend to error on the side of caution, building in a host of safety factors that substantially overestimate exposure to justify regulatory actions that may not be necessary.

Formalization of the precautionary principle as a policy tool began several decades ago. Early versions of the precautionary principle appeared in several

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international documents, including the United Nations World Charter for Nature (1982), the Nordic Council’s International Conference on the Pollution of the Seas (1989), the U.N. Environment Program’s Rio Declaration of Environment, Development (1992), U.N. Framework Convention on Climate Change (1992), and Convention on Biological Diversity.⁸

Environmental advocacy groups formalized the concept in 1998. That year, 31 activists from five countries met in Wingspread, Wisconsin, at the request of the North Dakota-based Science and Environment Health Network. The assembly produced the “Wingspread Statement,” which reads: “When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically.”⁹

Another version of this principle was essentially endorsed by 180 nations as a provision of the Cartagena Protocol on Biosafety in 2000. A section outlining the objective of the protocol notes that precaution—that is, regulation—should govern international movements of genetically modified (GM) products simply because they “*may* have adverse affects on the conservation and sustainable use of biological diversity taking also into account risks to human health.”¹⁰ [Emphasis added.] By getting policy makers to accept these definitions, environmentalists essentially declared that it is not necessary to scientifically demonstrate the need for an environmental health regulation.

Environmentalists have been able to use the precautionary principle to advance their agenda in a number of areas. Consider its impact on biotechnology. Author Bonner Cohen notes that GM crops have undergone extensive study by the world’s top scientific bodies—including the United Kingdom’s Royal Society, U.S. National Academy of Sciences, and World Health Organization—and they all report that GM foods pose no more risk than conventionally grown crops. Yet environmental groups have used the principle to claim that the public should not consume GM foods because the technology has not been proven safe. As a result of their campaigns against these crops, GM foods are so unpopular in Europe that supermarkets do not carry any such crops.¹¹

Such efforts have not worked as well in the United States, where GM foods are pretty common, but they have impacted developing nations. In 2002, Zambia and Zimbabwe’s governments locked up warehouses full of U.S. GM corn that was donated by the American government to help feed people during a famine in these two nations. The governments refused to distribute the food because leaders apparently did not want their citizens to eat GM foods because of concerns raised by environmentalists. Citizens in both nations eventually

broke into the warehouses and seized the corn.¹²

The environmental movement's precautionary principle was also used as the basis of an ambitious new regulatory program in Europe to regulate chemicals and other substances, which passed into law in December 2006. The European Union's (EU) chemicals policy, called REACH—which stands for Registration, Evaluation, and Authorization of Chemicals—will employ the precautionary principle by requiring companies to prove their products are safe before they are introduced into commerce. Before REACH, government officials had to demonstrate that a product is not safe *before* removing it from the market. REACH reverses this burden, demanding that firms conduct extensive tests to demonstrate product safety.

The text of REACH highlights the precautionary principle as the focus of the program. Article 1 notes that the provisions of REACH are “underpinned by the precautionary principle.”¹³ (The use of the precautionary principle in European legislation is not surprising, as the Treaty of the European Union also known as the Treaty of Maastricht,¹⁴ demands that EU regulatory bodies employ the precautionary principle in environmental legislation.)¹⁵ To achieve its goals, REACH demands a massive amount of data submission and testing from companies.¹⁶ It covers more than 100,000 chemicals, for which companies must submit data in an attempt to prove safety.¹⁷ The over-600 page legislation is expected to cost billions of dollars in direct compliance costs (€3.6 to €5.2 billion),¹⁸ substantially impact and potentially impede global trade,¹⁹ and produce unmeasured indirect costs.²⁰

REACH is precautionary, but it is not purely hazard-based. All covered chemicals are brought into the system based on the assumption of hazard, but the law's data submission and testing provisions attempt to set risk-based priorities. Chemicals dubbed “of concern” are assessed further. At that point, companies must show that, “risks associated with uses of these substances are adequately controlled or that the socio-economic benefits of their use outweigh the risks,”²¹ or be subject to regulation. Still, REACH remains precautionary in nature and may lead to unnecessary product removals. Unfortunately, the bureaucracy and other associated costs associated with REACH pose significant roadblocks to technological development and entrepreneurship, preempting economic growth in a way that cannot be measured.

Shortly after REACH was enacted in 2006, several American states—starting with California—began looking into enacting their own versions of this law. California passed a similar law, the Green Chemistry Initiative, and several other states have passed chemical regulation laws.²² In the United States Senate,

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Sen. Frank Lautenberg began working in tandem with environmental groups to build momentum for a U.S. version of REACH. To that end, he commissioned the Government Accountability Office to assess the need for revisions to the Toxics Substances Control Act—amendments that could transform that program into a REACH-styled law.²³ Sen. Lautenberg followed that report with the introduction of legislation designed to get the process moving in the direction of a U.S. REACH law. The first of these was the Child, Worker and Consumer Safe Chemicals Act; Rep. Henry Waxman (D-Calif.) introduced a companion bill in the House of Representatives.²⁴ Since then, Lautenberg and Waxman have introduced TSCA reform bills in the 110th, 111th and 112th Congresses.²⁵

Currently, U.S. environmental law does not overtly list the precautionary principle as a governing standard, yet precaution is the hallmark of many environmental policies. Federal pesticide regulations provide a perfect example of very precautionary—yet still risk-based—law. The 1996 Food Quality Protection Act (FQPA) was designed to replace an old standard called the Delaney Clause, which regulated pesticide residues on processed food. It prohibited the addition to food of any substance that had been shown to cause cancer in laboratory animals. That was such a precautionary standard that many lawmakers and agricultural interests feared it would eliminate many valuable agrochemical products. Passed by a Republican Congress seeking to curb regulatory excesses, FQPA adopted a risk-based standard that limited residues on all foods—both processed and unprocessed—to a level that ensured “a reasonable certainty that no harm will result from aggregate exposure.”²⁶ Despite contentions by supporters that the standard would be less stringent, the new law in fact proved *more* stringent than its predecessor. One observer commented: “No, you may not gain peace of mind when discovering that the new standard is stricter than Delaney, at least the way EPA and FDA was interpreting it.”²⁷

“No harm” suggests a zero-risk standard, and aggregate exposure considerations added a new level of precaution. The new law also demanded that regulators apply an additional 10-fold safety factor for any product to which children might be exposed, in addition to safety factors they already employed. Shortly after the FQPA was passed, University of Texas professor Frank Cross pointed out in a law review article that the EPA’s conservative risk estimates were already excessively cautious, overstating pesticide exposure thousands and even hundreds of thousands of times beyond the most likely actual exposure levels.²⁸ And the FQPA has added factors of caution beyond even that, leading to the removal of many products from the market.

For example, during the first 10 years of the FQPA’s life, the EPA

completed a 10-year study of 230 organophosphates and carbonates pesticides. It concluded that the Act demands that the agency ban 3,200 uses of pesticide products in these categories and place restrictions on 1,200 other uses. It deemed 5,237 uses as “safe” under the Act.²⁹ That is 46 percent of the uses of the 230 chemicals—a substantial increase of regulations using FQPA’s risk-based standard.

Attempts to curb such regulatory excesses have taken the form of regulatory oversight laws that focus on the regulatory process in general, rather than reforms to the underlying basis of these laws. By and large, these efforts have not proven particularly effective either in curbing precautionary environmental policy or in promoting rigorous risk-assessment and cost-benefit considerations as criteria for environmental regulation.³⁰

More recently, President Barack Obama gave a nod to the regulatory reform movement and risk-based regulation with Executive Order 13563,³¹ which called for many of the same regulatory reform provisions advocated by prior administrations, such as cost-benefit analysis and regulations that are “least burdensome tools for achieving regulatory ends.”³² While it expressed laudable goals, whether the administration can or actually wants to achieve them is another issue. Moreover, the order suffers from a flaw common to most regulatory reform efforts: They often run contrary to the dictates of actual laws and agencies rarely have the will to implement them.

In fact, despite the Executive Order, the Obama EPA is taking a more precautionary approach with its rules and regulations. For example, the agency’s Design for the Environment (DfE) program calls on companies to eliminate certain chemicals from their products voluntarily, largely based on hazard rather than actual risk.³³ The agency’s call that TSCA include “green chemistry” as a goal also embodies the idea that the use of certain “hazardous” chemicals is a problem regardless of the actual risk from exposure.³⁴

The agency’s implementation of TSCA is also illustrative of efforts by the Obama administration to enact more precautionary policies with little or no input from Congress. In September 2009, the administration launched its Enhancing EPA’s Chemical Management Program, which takes a more aggressive approach to implementing TSCA.³⁵ Recent news reports suggest that the EPA will accelerate these efforts because the chances that Congress can pass reform legislation before the 2012 elections appear dim.³⁶ Whether the administration succeeds in imposing bans and regulations without legislative reform remains to be seen. It is, however, already having an impact on the chemical marketplace by increasing media focus on certain chemicals it places on “concern” lists—

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again, focusing on hazard rather than risk—simply because no one can prove them 100 percent safe.

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TSCA and Public Health

Environmental activists who call for modernization of TSCA argue that its risk standard prevents the EPA from regulating where necessary to protect public health. TSCA “is not working,” says a coalition of environmental activists on the Safer Chemicals, Safer Families website.³⁷ They complain: “Over the course of the 34 years since TSCA was enacted, EPA has succeeded in restricting only limited uses of five chemicals.”³⁸ The implication here is that public health is at risk because TSCA does not allow the EPA to impose regulations that will solve serious health problems.

The suggestion that public health is at great risk because of TSCA is too weak is not scientifically supportable. Nonetheless, lawmakers should not measure the success of a law based on the number of regulations it produces. Their only concern should be on whether the law serves the interests of individuals and society overall. In fact, limited and targeted regulatory policy makes more sense given that the risks that TSCA regulates—trace chemicals in the environment—are extremely small.³⁹

For example, environmentalists often call for regulation on the grounds that man-made chemicals used in consumer products pose a serious cancer risk. Yet in their landmark 1981 study of the issue, renowned scientists Sir Richard Doll and Richard Peto outline the widely understood and accepted causes of cancer in the United States. According to Doll and Peto, 80 percent to 90 percent of cancers are caused by “environmental factors.” Although activists often trump this figure as evidence that industrial society is causing cancer, Doll and Peto explained that environmental factors are simply factors other than genetics—not pollution alone.

Pollution—including exposure to chemicals via consumer products—accounts for only 2 percent of all cancer cases. Tobacco use accounts for about 30 percent of all annual cancer deaths. Dietary choices account for 35 percent of annual cancer deaths.⁴⁰ Bruce Ames and Lois Swirsky Gold have come to similar conclusions, noting that smoking causes about a third of all cancers. They underscore the importance of diet by pointing out that the quarter of the population eating the fewest fruits and vegetables had double the cancer incidence than those eating the most. Finally, they conclude: “There is no convincing evidence that synthetic chemical pollutants are important as a cause of human cancer.”⁴¹

In contrast, environmentalists point to “evidence” of cancer caused by

man-made chemicals based on the fact that rodents get cancer when given massive doses of chemicals. Yet these studies have little relevance to humans exposed to trace amounts of those chemicals. In fact, high doses of many naturally occurring products—including broccoli, carrots, and coffee—also give rodents cancer.⁴² It is the dose that makes the poison.

Given the poor data related to chemicals and cancer, environmental activists have also suggested that chemicals pose another problem: Some man-made chemicals mimic human hormones and thereby cause a host of health problems, including developmental issues. In reality, trace chemicals found in consumer products and in the environment do not have enough potency to have any such effects. In fact, humans are exposed to such endocrine mimicking chemicals via a host of natural sources—such as legumes—that are hundreds of thousands of times more potent without ill effect.⁴³

Regulatory Activity under TSCA

Environmentalists charge that TSCA should be modernized simply because the law has accomplished very little in terms of regulatory activity. Activists at SaferChemicals.org argue, “When passed into law, TSCA approved more than 60,000 chemicals that were in existence prior to 1976; only 200 of the original 60,000 chemicals have been tested for safety; some uses of only five of these toxic substances have been restricted.”⁴⁴ The suggestion that the law yielded a pittance of regulatory activity is misleading. In fact, there has been significant regulatory activity under TSCA and much of it has proven excessive and unnecessary.

Congress originally designed TSCA to ensure safe use of industrial chemicals by granting the EPA authority to review both new and existing chemicals. TSCA covers any chemicals in commerce that are not regulated under other statutes. TSCA has no authority over drugs, pesticides, food additives, and cosmetics. Even with these exclusions, the scope of TSCA is substantial.

Despite activist hype, the EPA has issued rules covering thousands of new chemicals. In addition, it has forced chemical companies to restrict the use of various products under consent agreements.⁴⁵ The law allows the EPA to demand data when warranted, but unlike REACH, it does not demand gratuitous and expensive new data development collection or research on chemicals that have been used safely for decades. As the following illustrates, the agency can demand new testing for existing chemicals that it finds may pose “an unreasonable risk.” In addition, the act grants the EPA the authority to collect information from industry related to existing chemicals under a number of programs, both mandatory and voluntary.

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New Chemicals. The least controversial aspect of TSCA has been its regulation of new chemicals. Environmental activists do not discuss it much, thus underplaying the amount of regulatory activity under this program. TSCA’s Section 5 applies scrutiny to “new chemicals”—those introduced after the law passed as well as “significant new uses” of existing substances.⁴⁶ Manufactures of such substances must first notify the EPA before manufacturing or importing these chemicals, under what is called pre-manufacturing notice (PMN) procedures. PMN procedures include data submission regarding the substance. The EPA may require additional data submission if it determines that existing information is “not adequate to determine potential risk.”⁴⁷ According to the agency’s website, 90 percent of such chemicals are reviewed without the agency issuing regulations.⁴⁸ These chemicals can then be listed in the TSCA inventory. Other manufacturers are free to use them as well.

However, for the other 10 percent, the EPA may issue a Section 5(e) order that prohibits or otherwise limits use of the chemical. The EPA may issue these orders if it determines insufficient information exists:

- “[T]o evaluate the human health and environmental effects of the substance”; if the chemical “**may** present an unreasonable risk of injury to human health or the environment” [emphasis in original]; or
- If the chemical “will be produced in substantial quantities and may be anticipated to enter the environment in substantial quantities or there may be significant or substantial human exposure.”⁴⁹

The EPA explains that most Section 5(e) orders result in consent orders, which are agreements between the agency and manufacturers. These may demand toxicity testing once the chemical is used at a certain threshold amount as well as standards for safe handling and disposal.

Rather than negotiate a consent order, the EPA also has the option to issue a regulation related to new uses of existing chemicals, which is appropriately called a Significant New Use Rule (SNUR).⁵⁰ The agency usually issues a SNUR after issuing Consent Orders because the orders only apply to a specific company using the chemical. The SNUR applies the terms of the consent order to other companies that want to use a given chemical. In addition, any additional manufacturers who desire use a chemical that is subject to a SNUR must notify the EPA 90 days before such use, providing the agency time to review and potentially regulate such uses.⁵¹

A SNUR can limit or prohibit the use of a chemical if the EPA finds it poses an “unreasonable risk of injury to health or the environment.”⁵² The EPA can also place an injunction on use of a substance if test data are insufficient to determine whether a new chemical poses an unreasonable risk, holding up its use until test data is completed.⁵³ SNURs issued without a consent order are known as “non-5(e) SNURs.”⁵⁴

Despite claims that the EPA has not regulated much under TSCA, the agency has reviewed 44,000 new chemicals and placed 20,000 of them into the inventory of existing chemicals that the agency developed under the Act. The agency has also taken 3,899 regulatory and voluntary actions to restrict the use of new chemicals or gather data on them (about 10 percent of all premanufacture notices) and issued 1,320 consent orders, as well as non-5(e) SNURs covering 545 chemicals.⁵⁵ In addition, 1,705 premanufacture notices were “withdrawn often in face of action.”⁵⁶ In that case, while the EPA did not directly regulate the 1,705 chemicals, it used TSCA to prevent them from entering commerce. Whether any of the regulatory results of such actions were warranted is a separate issue. These activities may well have forced valuable products off the market, imposed needless restrictions, and forced companies to incur unnecessary costs. In any case, the suggestion that TSCA has produced little regulatory action is way off the mark.

Existing Chemicals Inventory. Under Section 8 of the TSCA, the EPA developed and continues to maintain an inventory of chemicals that fall under the law’s jurisdiction.⁵⁷ All chemicals listed on the inventory are regulated as “existing” chemicals. According to a 2007 Government Accountability Office (GAO) report, TSCA covers 82,000 chemicals of which 62,000 were already in commerce when the EPA began implementation in 1979, placing those within the category of “existing chemicals.” As noted, the inventory also now includes an additional 20,000 chemicals as a result of new chemical reviews. The agency also restricted use of five classes of chemicals that were in commerce when the law passed.⁵⁸

Existing Chemical Testing. For existing chemicals, TSCA does not demand that companies automatically begin testing all chemicals in the inventory to prove that the chemicals and mixtures they use are safe. The EPA may demand testing for any “existing chemical” under conditions outlined by Section 4 of the law.⁵⁹ Section 4 testing requirements employ a targeted approach that is intended to focus only on potentially problematic chemicals already in commerce.

The suggestion that TSCA has produced little regulatory action is way off the mark.

TSCA sets out several requirements before the agency can demand costly data development related to existing chemicals. In particular, the EPA can specifically demand development of new data and testing from industry using existing chemicals under one of two cases.⁶⁰ The first scenario—called an “A” finding because its codified at section (4)(a)(1)(A)—focuses on risk, allowing the EPA to mandate data collection if the chemical “may present an unreasonable risk of injury to health or the environment.”⁶¹ The EPA must also show that there is not sufficient data to effectively estimate the risk and additional testing is necessary to fill in data gaps.

In the second case—the “B” finding referring to (4)(a)(1)(B)—the EPA may demand data based on the fact that the chemical is—or will be—used in high volumes and leads to high human exposures or high environmental exposures. The second case also requires that the EPA show that existing data are insufficient and testing is necessary to develop such data. When the EPA does collect data, it must handle it carefully to prevent the release of confidential business information. However, it should be noted that the EPA also regularly collects existing data on these chemicals under another section of the law (Section 8), which is discussed below.

In both cases, the law does not require EPA to *prove* risk or demonstrate excessive exposure. Instead, it states the EPA can act if the chemical “may” pose a risk. Attorney William Rawson offers a helpful discussion on this topic in 2006 comments before the Senate Environment and Public Works Committee. He points out that a 1988 court ruling on the topic allows the EPA to take action based on the mere “potential” that a chemical might pose a risk.⁶² Once the EPA establishes that a chemical poses “more than theoretical probability” of a risk, industry must demonstrate otherwise. In 1990, the agency established Policy B in response to another court challenge.⁶³ Rawson notes that in Policy B, the EPA clarified the criteria it uses to demand testing by specifically enumerating the exposure levels that constitute “substantial exposures” for various groups of people—workers, consumers, and the general population. “Since then,” Rawson points out, “these criteria have proven relatively easy to apply.”⁶⁴ Thus, it is not inordinately difficult for the EPA to demand testing.

Moreover, contrary to activist hype that TSCA places no burden on businesses to test their products, the law states: “It is the policy of the United States that adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and development of such data be the responsibility of those who manufacture and those who process such chemicals and mixtures.”⁶⁵

While the EPA does not demand testing on every chemical in commerce, TSCA is designed to focus on those chemicals that possess some probability that they carry health risks (albeit often quite low). To that end, the EPA developed the Master Testing List (MTL). The EPA list development and testing relies on voluntary participation by industry as well as on agency issuance of testing rules under TSCA. The EPA reports that it has more than 500 individual existing chemicals on the MTL. The EPA is about to remove 70 chemicals because testing is complete.⁶⁶ It has begun testing on 300 chemicals and is developing testing actions for 200 of those chemicals.

Chemicals that do not appear on the MTL still undergo testing in other venues. Companies voluntarily test their products to ensure safety because they cannot make profits by making their customers sick. Safety is so critical that there are myriad associations and voluntary programs through which industries employ independent scientific panels to test their products.⁶⁷ In addition, many of the raw chemicals covered under TSCA are subject of regulations and voluntary programs regulating the final consumer products that compose them.

For example, consider formaldehyde. It is regulated under TSCA but it is also studied and regulated by numerous bodies around the world including: the World Health Organization's International Agency for Research on Cancer (IARC), the Department of Labor's Occupational Safety and Health Administration (OSHA), Food and Drug Administration, the EPA's Office of Hazardous Air Pollutants (under the Clean Air Act), Consumer Product Safety Commission (CPSC), and numerous state laws.⁶⁸ It is subject to study by overseas governments as well, such as the European Food Safety Authority.⁶⁹ And numerous independent research bodies have evaluated its safety, including: the American Association for the Advancement of Science, American Chemistry Council, American Forest and Paper Association, Can Manufacturers Institute, Composite Panel Association, Personal Care Products Council, Kitchen Cabinet Manufacturers Association, Methanol Institute, National Funeral Directors Association, and likely others around the world.⁷⁰ Companies that use formaldehyde in their products also conduct testing. Under TSCA industry must report to the EPA under Section 8 (discussed more below) any such research that is not already publicly available. Based on the research, governments around the world allow use of formaldehyde because it poses low risks at current exposure levels.

The Department of Housing and Urban Development and Federal Emergency Management Agency also regulate formaldehyde, but activists maintain that this is still not enough. They want TSCA reform to demand more testing and allow even greater regulation under a precautionary, rather than

Companies voluntarily test their products to ensure safety because they cannot make profits by making their customers sick.

REACH involves spending billions of dollars looking for a needle in a haystack that most likely does not even exist.

science-based risk standard.⁷¹ Such activists and others—including the Government Accountability Office—maintain that these relatively strict standards prevent the EPA from effectively demanding data that could help reduce public health problems.⁷² Accordingly, they advocate a REACH-style program that mandates testing and data on all chemicals under TSCA regardless of whether there is good cause for such research investment.

However, based on the relatively low risks associated with the trace chemical exposures that TSCA regulates, REACH-style data mandates are unlikely to improve public health but will certainly increase needless bureaucracy. In fact, REACH requires such data on more than 100,000 chemicals, creating a regulatory monster that indiscriminately demands expensive data collection, even for well-known chemicals used safely for decades for which the possibility of harm is remote.⁷³ REACH involves spending billions of dollars looking for a needle in a haystack that most likely does not even exist.

EU bureaucrats assured the world that this process would not be too complicated or expensive. Yet as REACH implementation unfolds, even its supporters are getting anxious. Toxicologist Thomas Hartung and chemist Costanza Rovida lament: “It was expected that 27,000 companies would submit 180,000 pre-registrations on 29,000 substances. Instead, some 65,000 companies made more than 2.7 million pre-registrations for in excess of 140,000 substances. REACH aims to complete data collection on these substances by 2018.”⁷⁴ Hartung and Rovida suggest that the total number of substances will shrink from 140,000 pre-registrations to 68,000 after errors and duplicates are corrected. However, that is a conservative estimate. The reality is that as new substances are developed, they too must be registered.

The EU’s ability to adequately study and draw conclusions about these substances is dismal. Before REACH, it took EU bureaucrats 10 years to assess 27 substances under the old chemicals law.⁷⁵ REACH is destined to be a massive bureaucratic exercise conducted in a sloppy and arbitrary fashion. It will allow random regulation because it is based on the arbitrary standard that is the precautionary principle.

Everyone stands to lose as prices rise for consumers, businesses fail under the weight of bureaucracy, and valuable products are removed from the marketplace. We will never know what life-saving, life-enhancing products were never developed because of REACH regulations, what small businesses were never created, and how many firms were forced to close.

Only governments engage in—or mandate others to pursue—such foolhardy investments. Consider what the world would be like if businesses

routinely spent limited resources on a regular basis to fund studying topics that pose a very low probability of yielding valuable, new information. Far less funding would be available for the development of medicines, helpful consumer products, and even some of the amenities that green advocates deem unimportant—yet consumers enjoy—like pleasing fragrances we use in our homes, on our clothes, and even to attract the opposite sex. Such policies are nothing more than a recipe for stagnation.

The “test-everything-no-matter-the-cost” philosophy also takes a toll on test animals. Testing of animals is a necessary part of ensuring public safety on which both the private and public sectors have long relied. It is also a crucial tool in the discovery of medical treatments. Humane treatment of animals demands that such testing be done when necessary, but not done when benefits or new information are unlikely generated.

Needless levels of testing will produce a system that promotes a massive amount of gratuitous animal testing, as has proven the case with REACH. Hartung and Rovida point out that REACH requires 20 times more animals for the research than estimated by EU officials. They further note that REACH will require 54 million vertebrate animals and will carry a price tag of €9.5 billion (\$13.5 billion) over 10 years.⁷⁶ As a point of comparison, they note that the EU used only 90,000 animals annually for testing new chemicals in the pre-REACH era.⁷⁷

Ironically, as the European Union demands massive amounts of testing under REACH, in 2003 it passed a ban on all animal testing for cosmetics by 2011. Under the European Union’s Cosmetics Directive, testing final products has already been phased out and some testing on ingredients with some exceptions. The last phase was to end all cosmetics testing by March 2011, but the government has extended the deadline to 2013 because there are not good alternatives to ensure public health and safety. And while REACH imposes largely indiscriminate testing mandates, the cosmetics industry engages in a very limited testing regime only where necessary to ensure public health. For example, the Cosmetic, Toiletry and Perfumery Association notes that the number of animal tests in Europe to ensure cosmetic safety in 2008 amounts to just 1,510 animals out of a total more than 12 million animals used for scientific testing.

In comparison to REACH’s massive testing mandates, TSCA currently employs a targeted and reasonable approach that limits the impact and cost of testing. It recognizes that excessive mandates divert resources from other valuable uses—such as development of technologies to make life healthier, safer, more prosperous, and more enjoyable. After all, if businesses may invest heavily to

Needless levels of testing will produce a system that promotes a massive amount of gratuitous animal testing, as has proven the case with REACH.

search for unlikely risks and problems associated with their technologies, they invest less in other items that would increase their bottom line—and enrich the lives of consumers.

Existing Chemicals Reporting Requirements. Although TSCA does not mandate testing, it does demand submission of existing data to the EPA both on a regular basis and upon demand for specific chemicals.

- **Chemical Data Reporting Rule (CDR).**⁷⁸ Requires regular reporting to the EPA (every four years) on the volume of all existing chemicals listed in the EPA inventory that firms use at specific sites.
- **Preliminary Assessment Information Rule (PAIR).** Designates certain chemicals by regulation that are subject to additional reporting related to production volume, releases into the environment, and worker exposure. The EPA has applied the PAIR rule to examine hundreds of chemicals.⁷⁹
- **Health and Safety Data Reporting Data Rule.** Requires companies to submit unpublished health and safety studies to the EPA.⁸⁰
- **Substantial Risk Rule.** Requires companies to report unpublished safety studies and provide any information indicating that a chemical poses substantial risks to injury to health or the environment.⁸¹
- **Adverse Reactions Rule.** Requires manufacturers and importers to keep a record of allegations of adverse public health reactions to humans or the environment and provide it to the EPA upon request.⁸²
- **Export and import notifications.** Requires exporters of TSCA-regulated substances to provide notice to the EPA before exporting. Importers must comply with TSCA regulations that apply to manufacturers.⁸³

The EPA's research on existing chemicals is aided by the Interagency Testing Committee, an independent research group that works to identify chemicals that may pose potentially higher-than-average risks, have limited available risk data, or both.⁸⁴ The committee meets every six months and develops a priority testing list consisting of chemicals for which it recommends that the EPA demand more data.

In addition, the Interagency Testing Committee has been active reviewing chemicals. Its activities since its creation in 1976 include: producing 67 reports, recommending information reporting or testing for about 4,500 chemicals, and reviewing about 1,700 confidential business information reports submitted in response to PAIR rules. It has also reviewed 2,200 studies submitted in response to voluntary solicitations to industry and about 10,200 studies submitted in response to the Hazard and Safety Data Reporting Rule.⁸⁵

Contrary to environmentalist claims that the EPA has done close to nothing related to existing chemicals, a 2009 Congressional Research Service study shows that the EPA was very active in regard to TSCA.⁸⁶ During 1976-2005, the agency issued 33 PAIR rules that require additional data collection on 1,200 chemicals.⁸⁷ According to the EPA, by 2006 it received about 16,500 notices under the Substantial Risk Rule since 1977.⁸⁸

Voluntary Data Collection Initiatives for Existing Chemicals. Over the years and under the leadership of different political parties and presidents, the EPA has employed a host of different strategies in an attempt to use the information it collects to prioritize risks and assess the need for regulations. In its early years, the agency focused on developing the rules noted above, lists by the testing committee, regulations on six existing chemicals, new chemical regulations and the like.⁸⁹ But eventually, new efforts to collect more data often via voluntary means and set priorities for risk categorization followed.

During the Clinton administration, the agency launched the High Volume Chemicals Program, part of an international effort to collect and share data on chemicals used in high quantity—produced in or imported into the United States at or above 1 million pounds per year. The EPA launched the program in 1998 in partnership with Environmental Defense, the American Petroleum Institute, and American Chemistry Council. It called upon companies to voluntarily provide and make public research data on these chemicals. According to the EPA, the program collected information on more than 2,200 HPV chemicals, along with submission of existing data from 6,500 published studies, and more than 8,100 then-unpublished studies.⁹⁰ This data is now available publicly online.⁹¹

During the presidency of George W. Bush, EPA Administrator Stephen Johnson announced the Chemical Assessment and Management Program (ChAMP) in 2007. As the agency explains on its website, ChAMP “was designed to develop screening-level hazard, exposure, and risk characterizations” for HPV chemicals as well as “moderate production volume (MPV)” chemicals, those produced or imported in quantities of 25,000 pounds or greater a year.⁹²

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The program was designed to make sense of and use the considerable data and research collected through TSCA and its voluntary programs—such as the HPV initiative—considering such things as hazard, exposure and actual risk levels. It covered an estimated 6,750 chemicals.⁹³

If chemical manufacturers had to prove complete safety, products as valuable as penicillin might never gain approval.

TSCA Risk-Based Regulatory Standard for Existing Chemicals. Environmental activists abhor TSCA’s risk standard, noting: “Instead of requiring chemical manufacturers to demonstrate that their products are safe before they go into use, the law says the government has to prove actual harm in order to control or replace a dangerous chemical.”⁹⁴ This is surely a good standard, akin to demanding that a court of law prove the accused is guilty before placing him in jail. After all, if chemical manufacturers had to prove complete safety, products as valuable as penicillin might never gain approval. Instead, the benefits of all products and technologies must be weighed against potential risks. TSCA does this quite well.

TSCA’s Section 6 applies a reasonable risk-based standard, which requires that the agency weigh the risks associated with the substance versus the risks and costs associated with potential regulations. Specifically, the EPA may regulate chemicals on the TSCA inventory when a chemical poses an “unreasonable risk of injury to health or the environment.”⁹⁵ The EPA explains on its website:

“[U]nreasonable risk involves the balancing of the probability that harm will occur and the magnitude and severity of that harm against the effect of a proposed regulatory action on the availability to society of the expected benefits of the chemical substance.”⁹⁶

If the EPA finds that a chemical does in fact pose such an unreasonable risk, it may prohibit its use, impose regulations limiting its use, mandate record keeping, set disposal regulations, require posted warnings related to its use, and other measures. It states further that the agency must apply such restrictions “to the extent necessary to protect adequately against such risk using the least burdensome requirements.”⁹⁷ When issuing a rule, the agency must consider:

- Effects and exposure of the substance on humans;
- Effects and exposure to the environment;
- Benefits of various uses and the availability of substitutes; and
- Economic consequences of the rule as it relates to the economy, small business, technological innovation, the environment, and public health.⁹⁸

This is a rational and solid risk-based standard that is quite unique within U.S. environmental law. It directs the EPA to focus on scientifically robust, well-designed studies. It also demands that the agency consider both cost-benefit considerations and potentially adverse outcomes of its regulatory actions. Citizens should demand at least as much before any governmental body issues regulations that undermine the freedoms necessary for society to progress and innovate.

Yet environmental activists and their allies in Congress complain that this standard is too stringent and has prevented the EPA from regulating many chemicals that may pose a risk to human health, although there is no evidence that the absence of regulations has caused a single illness. Safer Chemicals, Safer Families claims that, “The burden of proof TSCA places on the EPA to prove actual harm before it can regulate a chemical and to show its regulatory action is the least burdensome of all options is so onerous that it prevented the EPA from restricting asbestos, a known human carcinogen.”⁹⁹ They refer to the fact that the agency’s TSCA standard for asbestos was vacated by a federal court because it violated TSCA’s cost-benefit test. But the asbestos ruling demonstrates how TSCA’s risk-based standard protects consumers from unwarranted and poorly conceived regulations.

In the 1980s, exposure and use of asbestos were already well regulated by OSHA and other EPA regulations to ensure safe management of these chemicals under other statutes. Still, the EPA wanted to impose even more stringent regulations on asbestos by using its authority under TSCA. In 1989, the EPA released a very ambitious TSCA rule banning most asbestos uses, affecting dozens of businesses and applications.¹⁰⁰ The agency concluded that this standard would prevent somewhere between 148 and 202 cancer cases at a cost of \$458.89 million to \$806.51 million or \$3 million to \$4 million per cancer case.¹⁰¹

Given the scope of this regulation and its impact on so many industries and consumer products, it was imperative that the agency justify its decision based on science and the risk-risk considerations set under the TSCA statute. That included consideration of potential risks that might result from the rule itself. As part of the cost-benefit side, TSCA directs the EPA to employ the “least burdensome regulation” necessary protect public health.

A federal court eventually ruled that the EPA failed to meet those basic requirements and could endanger public health and safety with this rule. The Fifth Circuit Court of Appeals opinion in *Corrosion Proof Fittings v. EPA* stated:

We conclude that the EPA has presented insufficient evidence to justify its asbestos ban. We base this conclusion upon two

TSCA’s risk-based standard protects consumers from unwarranted and poorly conceived regulations.

Asbestos-related illnesses are not likely caused by the type of asbestos that the EPA set out to ban.

grounds: the failure of the EPA to consider all necessary evidence and its failure to give adequate weight to statutory language requiring it to promulgate the least burdensome, reasonable regulation required to protect the environment adequately.¹⁰²

While asbestos can be dangerous if exposure is not managed (particularly worker exposure, which is managed under OSHA regulations), the court held that an all-out ban on most asbestos uses could increase fatalities. For example, it stated:

EPA failed to study the effect of non-asbestos brakes on automotive safety, despite credible evidence that non-asbestos brakes could increase significantly the number of highway fatalities, and that the EPA failed to evaluate the toxicity of likely brake substitutes. As we already mentioned, the EPA, in its zeal to ban asbestos, cannot overlook, with only cursory study, credible contentions that substitute products actually might increase fatalities.¹⁰³

Green activists are right about one thing: Asbestos can cause cancer and many workers exposed to them have developed lung cancer as a result. However, these groups—like the EPA—present the situation in a very misleading way by failing to distinguish between different types of asbestos and the scenarios in which they pose risks. In particular, asbestos-related illnesses are not likely caused by the type of asbestos that the EPA set out to ban.

Asbestos health risks are related to the length, shape, diameter of asbestos fibers. A study produced by the American Council on Science and Health (ACSH) details the research findings on asbestos, particularly risk differences between the various fibers.¹⁰⁴ It points out that amphibole fibers are the ones associated with the greatest risks because they are long, thin and easily embed in human tissue. When inhaled, amphibole fibers remain in tissue for a long duration. High exposures over a long period of time increase the propensity for cancer, mesothelioma (cancerous or benign tumors), and asbestosis (scarring of lung tissue that can impede breathing) late in life. Any risks related to such fibers reside in workplaces. Fortunately, as ACSH points out, improved safety measures in the workplace greatly reduces this risk.

The asbestos most commonly used in the United States—and used in most of the products the EPA attempted to ban—are chrysotile asbestos fibers. These fibers are short and wide structures that do not easily embed into human

tissues and pose a far lower risk. They comprise more than 99 percent of asbestos uses in United States.¹⁰⁵ Numerous studies on workers exposed to chrysotile asbestos in friction control industries—such as workers for brake manufacturers and automotive break repair workers—do not find a significant cancer risks.

ACSH concluded:

Ambient asbestos exposure does not appear to be a significant risk factor for asbestosis, lung cancer, or mesothelioma for the general population. These diseases have historically been largely confined to occupational settings in which asbestos exposures were not adequately controlled, or as a result of significant over-exposure, often involving years of occupational exposure. Despite some divergence from earlier thinking, more recent analyses of certain occupational settings (e.g., brake industry workers, automechanics) suggest that asbestos exposures in these industrial settings were not causally related to respiratory disease or lung cancer.

Accordingly, the EPA's decision was out of line, making the court rebuke of the agency under the TSCA standard clearly a reasonable and sound public policy. In fact, the EPA's demonization of asbestos has led local governments and private industry to substantially reduce uses that could have life-saving applications. Although the EPA wanted to ban them under TSCA, history also shows that politically forced substitution of asbestos has had serious consequences. Fires at theaters and other public places, such as schools, regularly took human lives until asbestos insulation for tiles, curtains, and the like was introduced, as detailed in several case studies by author John Berlau.¹⁰⁶

The EPA and environmental activists led a campaign against the products, which led the Port Authority of New York City to halt asbestos use when building the World Trade Center Towers—failing to apply asbestos to the top floors of the first tower and not applying it at all in the second. Had the city used asbestos instead of switching to a substitute product, explains Berlau, heat from the fire may have been controlled at least long enough for thousands of more people to escape before the buildings collapsed on 9/11. The replacement product, fiberglass, breaks down at 1,100 degrees Fahrenheit, whereas asbestos hold up to 2,100°F.¹⁰⁷ A report produced after 9/11 by the National Institute of Standards and Technology concluded that the temperatures during the fires in the World Trade Center Towers never rose beyond 1,800°F.¹⁰⁸ “Even with the airplane impact and jet-fuel ignited multi-floor fires, which are not normal building

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Despite TSCA's tough risk standard, the EPA has been able to regulate several other existing chemicals.

fires, the building would likely not have collapsed had it not been for the fireproofing,” noted the lead investigator on the report.¹⁰⁹

Sadly, the unwarranted elimination of asbestos in many places continues to pose a threat. In February 2003, highly flammable foam soundproofing tiles at a nightclub in West Warwick, Rhode Island, caught fire, killing about 100 people. Before the political crusade against them, asbestos were also the product of choice for soundproofing tiles.¹¹⁰ Had they been used in the nightclub rather than the substitute, the fire would likely not have spread, or even started. Unfortunately, there surely are many other, recorded and unrecorded, examples of fire-related injuries and deaths that could have been prevented or significantly mitigated with asbestos-related products.

Despite TSCA's tough risk standard, the EPA has been able to regulate several other existing chemicals. Supposedly, these chemicals are dangerous enough to meet the risk standard. However, it is worth noting that the evidence against even these chemicals is not as clear as some believe. In fact, the story behind each underscores the contention that the trace level chemicals that TSCA regulates do not pose significant health concerns. These chemical bans include:

- **Polychlorinated Biphenyls (PCBs).** PCBs are a class of chemicals that have valuable applications in electrical and consumer products because of their flame-retarding qualities. The EPA banned PCBs in 1978, with the exception of those totally enclosed within products (limiting public and environmental exposure). In addition, the EPA may authorize specific uses by issuing a rule. However, the agency has also proposed phasing out these, limited uses.¹¹¹ According to the agency, this ban and earlier bans of other uses are justified because sufficient rodent data indicate that PCBs are probable carcinogens. In these studies, rodents were exposed to very high levels not particularly relevant to the low levels that humans might experience. Rodents get cancer when exposed to similarly high doses of fruits and vegetables, which are safe under normal exposures.¹¹² In comparison, there is little evidence of risks to humans. Human studies related to PCBs, fall within a category that the International Agency for Research on Chemicals calls “limited.”¹¹³ In fact, human studies related to relatively high worker exposures are inconsistent and contain too many confounding factors to draw any real conclusions.¹¹⁴

- **Fully Halogenated Chlorofluoroalkanes (CFCs).** The EPA banned “nonessential uses” of CFCs, such as propellants in aerosol spray containers, in 1978 because of potential impacts on the ozone layer. However, this regulation was eliminated in 1995 when the EPA replaced it with a complete ban under the Clean Air Act and to comply with the Montreal Protocol on Substances that Deplete the Ozone Layer, which took effect in 1989.¹¹⁵ The costs of this ban were significant,¹¹⁶ while the impacts of CFCs on the ozone layer were exaggerated, as CEI analyst Ben Lieberman points out in his study on the topic.¹¹⁷
- **Dioxin.** In 1980, the EPA issued a TSCA rule on dioxin related to waste disposal, which regulations under the Resource Conservation and Recovery Act superseded in 1985.¹¹⁸ But dioxin is common in nature and appears at inconsequential levels in our food supply. The EPA has also continued a controversial assessment of dioxin for decades, but this chemical is not the bogeyman that activist greens and the agency contend.¹¹⁹ Scientist Michael Gough points out: “Information about the possible human health effects of dioxin is available from studies of chemical plant workers, sprayers of dioxin-contaminated herbicides, and other exposed people. No human illness, other than the skin disease chloracne, which has occurred only in highly exposed people, has been convincingly associated with dioxin.”¹²⁰
- **Hexavalent Chromium.** In 1990, the EPA banned hexavalent chromium-based water treatment chemicals under TSCA.¹²¹ It is true that some studies have linked Hexavalent Chromium—which is also known as chromium-6—to lung cancer among workers who inhaled high levels of it over a relatively long time period, but those studies are not very relevant to ingestion of trace levels in drinking water. Yet the evidence of significant risk from chromium in U.S. drinking water is weak. The EPA nonetheless continues to study impact of oral exposure to Chromium 6 in part because that is the subject of a class action lawsuit related to chromium 6 contamination of the water supply in Hinkley, California. This story was popularized

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by the movie *Erin Brockovich*, which garnered considerable media attention and politicized the issue. Despite the high levels in the water, researchers have never found evidence of any kind of cancer cluster in Hinkley. Recent research has again confirmed that cancer rate for the area is actually lower than that of other, similar areas. And the EPA's September 2010 draft risk assessment on chromium-6 states, "The epidemiologic data are not sufficient to establish a causal association between exposure to hexavalent chromium by ingestion and cancer."¹²² Instead the EPA bases its draft assessment classification of "likely to be carcinogenic to humans" based mostly on rodent studies.¹²³ But those studies, involved rodents that ingested at relatively high levels of the chemical in drinking water over two years, a long time frame in the life of a rat. The relevancy of these studies to humans exposed to far lower levels on a short term basis is tenuous.

The Enhancing EPA'S Chemical Management Program

The Obama administration's EPA Administrator, Lisa Jackson, initially continued with the Bush administration-created ChAMP program, while she called on Congress to pass a bill reforming TSCA to apply a more precautionary regulatory standard. As legislative reform languished, Jackson launched the Enhancing EPA's Chemical Management Program in 2009, replacing the ChAMP program with a more expansive effort that includes regulation rather than voluntary data management and collection. The new program includes a number of new initiatives to increase data collection, set regulatory priorities, and more aggressively implement regulatory programs under TSCA.¹²⁴ Key programs include new regulatory risk management actions, chemical action plans (CAP), and a new program to prioritize chemicals for review and assessment.

New Regulatory Risk Management Actions. Under this heading, the EPA has developed "risk management plans" for certain chemicals which the agency decided required greater regulation. Actions include a new rule to beef up regulations related to remodeling projects that involve lead paint, as well as rulemakings on banning the use of lead weights in tires, to ban mercury in a number of products, on the use of formaldehyde use in pressed wood products, to review the remaining legal PCB uses, and to require notification of new consumer uses of substances called glymes.¹²⁵

Some of these actions have proven controversial, such as the EPA's approach to regulating remodeling activities in homes that involve disturbing lead-based paint. Under a 2008 rule, the agency required that anyone contracted to perform home remodeling and repairs must take an eight-hour course and gain certification before they could take on any projects that involve homes that might contain lead paint—those built before 1978.¹²⁶ Before beginning a project, remodelers must also test the areas of the pre-1978 homes where remodeling is to take effect for lead paint. If lead paint is present, the contractor must implement “lead-free work practices,” as defined by the regulation. According to the EPA, these practices are designed to contain the work area to minimize dust, and ensure thorough cleanup.

Originally, the rule allowed homeowners who did not have children six years of age and younger or pregnant women to opt out of lead-safe work practices, but the Obama EPA eliminated that provision in 2010 after it launched the Enhancing EPA's Chemical Management Program.¹²⁷ According to EPA estimates, elimination of the opt-out rule increased regulatory costs by more than \$500 million in the first year, \$300 million the second year, and then more than \$200 million the following years.¹²⁸

The National Association of Home Builders opposed the elimination of the op-out option rule because, “it substantially increases the cost of the rule without providing a corresponding benefit ...NAHB is concerned that home owners will turn to unlicensed contractors, decide to do the project themselves, or defer maintenance instead of paying the additional \$2,400 our members estimate is added to the cost of every project subject to the regulation.”¹²⁹ The NAHB has recently argued its case before the D.C. Circuit Court in an attempt to reverse the op-out option rule, and is awaiting a decision.¹³⁰

The costs of the rule are high for small business. A recent article in *The Fiscal Times* explains how one small woman-owned remodeling company in Ohio is nearly going out of business trying to cover the costs of complying with the rule: “The new rule's detailed compliance requirements, related paperwork, and purchases of EPA required equipment added thousands of dollars to the cost of doing business and made it much harder for her [owner Kathy Faia] to compete for remodeling contracts. Business has dropped off by more than two thirds, and she recently had to lay off one of her workers. ‘I'm just barely hanging on,’ she says. ‘They [the EPA] are over-regulating and sucking all of the fun out of the remodeling business.’”¹³¹

While expensive and burdensome for homeowners and remodelers, the EPA's elimination of the op-out provision is unlikely to solve many significant

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The CAP program has already proven controversial, as it remains unclear why the EPA picked certain targets.

health issues. Lead in the home can indeed be an issue for children under six who are exposed to lead paint on a chronic basis. Fortunately, lead paint exposures to children have diminished over the past couple of decades.¹³² Since 1997, the federal Centers for Disease Control and Prevention reports that the number of children with elevated blood levels found in their surveillance samples has declined from 7.61 percent to 0.83 percent by 2008.¹³³ Remaining health problems exist largely in older homes that are not properly maintained, often in low-income neighborhoods where residents cannot afford proper repairs and upkeep.¹³⁴ Requiring homeowners without any children in their home to comply with the lead rule does nothing to address that problem and likely provides zero health benefits. Moreover, regulations that make remodeling more expensive for these older homes could exacerbate problems as onerous mandates discourage repairs that would otherwise reduce lead paint-based risks.

Chemical Action Plans (CAP). This new program targets “chemicals of concern,” which the agency says it will identify through “EPA’s review of available hazard, exposure, and use information, and will outline the risks that each chemical may present and what specific steps the Agency will take to address those concerns.” According to the agency, the program “intends to utilize the full array of regulatory tools under TSCA to address risks, including authority to label, restrict, or ban chemicals under Section 6 of TSCA.” It already developed and posted plans on its website pertaining to:

- Benzidine Dyes
- Bisphenol A (BPA)
- Hexabromocyclododecane (HBCD)
- Long-chain perfluorinated chemicals (PFCs)
- Methylene Diphenyl Diisocyanate (MDI)
- Nonylphenol and Nonylphenol Ethoxylates
- Penta, octa, and decabromodiphenyl ethers (PBDEs) in products
- Phthalates
- Short-chain chlorinated paraffins
- Toluene Diisocyanate (TDI)

The CAP program has already proven controversial, as it remains unclear why the EPA picked certain targets. In addition, the potential benefits of regulation appear low while the costs could be substantial, some items on the list come from what might be called a list of “usual suspects,”—chemicals that activists have targeted in the past, such as phthalates, bisphenol A, and

perfluorinated chemicals. Despite what environmentalists say about the need for information, these chemicals have been studied *ad nauseam* and new research is unlikely to add much information about their impact on human health—though it might help capture headlines and instill fear where it need not exist.

Among the potential outcomes of the CAP program is the addition of chemicals to a Chemicals of Concern List, via a provision of TSCA that has never been implemented. Section 5(b)(4) of TSCA states that the EPA administrator “may compile and keep current a list of chemical substances” that he/she finds “presents or may present an unreasonable risk of injury to health or the environment.”¹³⁵ In making the list, the administrator “shall consider” the effect on health and the environment and the magnitude of exposures. The EPA may use information it has collected via the HPV program to demonstrate that a chemical should be listed.¹³⁶ TSCA also requires the agency to provide opportunities for oral and written comments before listing a chemical. Thus far, five CAPs have proposed listing of the following chemicals and chemical categories: BPA, phthalates, HBCD, nonylphenol and nonylphenol ethoxylates, and PBDEs.¹³⁷

The mere listing of chemicals—particularly on a “concern” list—can create its own hazards. In an analysis for the *Daily Environment Report*, former EPA Office of Pollution Prevention and Toxics Director Charles M. Auer (2002-2009) and colleagues point out potential economic and social impacts that listing of chemicals can produce. They note that similar impacts have resulted from other listings of chemicals by the EPA under the Clean Air Act and Safe Drinking Water Act. An EPA “chemicals of concern list,” they maintain, would possibly produce the following results:

- Chemical manufacturers are likely to see it as a virtual “black list” and will be concerned that the risk basis for the listing may be misunderstood or overstated.
- Downstream commercial entities may see it as providing reason for them to investigate alternative substances to formulate safer products, restrict the distribution of products containing listed chemicals, or both.
- Environmental groups will likely exploit listings to advance their political crusades against certain “problem chemicals.”
- States may draw chemicals from the list for restrictions or bans.
- Congress may use the list to develop regulatory priorities for TSCA reform legislation.¹³⁸

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*Random elimination
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The U.S. Chamber of Commerce explained to the Office of Management and Budget how an EPA proposal pending review there would officially list several chemicals:

In 2010, an article in *Politics Daily* quoted an EPA spokesperson as saying: “Although the list is not a legal ban, it does serve as a signal to the marketplace that the agency wants these substances phased out.” EPA lacks the legal authority to “signal to the marketplace that the agency wants these substances phased out” absent sufficient evidence to support a § 6(a) rule. Yet, it appears EPA believes a considered, initiated or actual listing could be the functional equivalent of a ban, causing consumer and other product manufacturers to shift away from the listed chemicals due to the wave of tort actions and advocacy group actions that will follow in the wake of the Agency’s announcements and determinations.¹³⁹

In fact, when the EPA announced this program, retail giants Costco, Walmart, and Target all stated to the press that the list will impact their purchasing decisions, causing them to reduce and perhaps eliminate products containing listed chemicals.¹⁴⁰ Target and Walmart have already begun to take action. Walmart, for example, had already begun replacing products containing phthalates in children’s clothing and footwear.¹⁴¹ Such voluntary product eliminations may appear to either be beneficial or innocuous, but that line of reasoning ignores the benefits the products bring and the potential risks associated with alternatives.

Such random elimination of valuable products and technologies from the market amounts to a recipe for stagnation. First, it wastes the investments and ingenuity that developed the products in the first place. Second, it requires additional effort and investment to develop alternatives and for reformulations of products that used the original products as ingredients. These costs mean that fewer resources are available for research and development of other potentially life-enhancing initiatives.

Moreover, EPA listing, followed by voluntary replacements of “non-essential” uses of a chemical, builds pressure for bans that may affect critical applications. For example, Walmart and Target have begun to respond to the EPA and green activists’ desire to eliminate phthalates in some consumer products like shower curtains, but that is not where environmental activists would like the phase-out to end. They have campaigned for more than a decade to eliminate phthalates—which are used to make soft, flexible plastics—in life-saving

medical devices and blood bags.¹⁴² Additional EPA attacks on these products via government “blacklisting” could result in the loss of human life and increased pain and suffering in hospitals should replacement products not perform to the same level.

For example, phthalates help make vinyl tubing that does not kink, keeping critical medicines and blood flowing to patients—something that kidney dialysis patients well understand is crucial. It also makes lightweight, flexible blood bags that help preserve, store, and strategically manage our nation’s blood supply. A study commissioned by the American Chemistry Council explains:

Before the invention of plastic blood bags, blood was collected in glass bottles. Two common issues with glass bottles are inadequate sterilization, which induces contamination of the blood, and air or gas bubbles, which can cause complications in the bloodstream. The advent of the plastic blood-collection bag was a significant breakthrough in the history of blood collection and banking. Because blood bags are disposable, the external contamination of donated blood is reduced to unprecedented levels. Flexible and unbreakable, blood bags were also important to the development of ambulatory medicine. Furthermore, the plasticity of blood bags facilitates the separation of blood components and the resilience allows not only easy transportation but also economical freezing of blood and blood products. Modern blood banking depends on PVC [polyvinyl chloride]—it has functional properties that are difficult to replicate in a simple, cost effective manner.¹⁴³

Activists might not trust an industry-funded study, but the benefits of PVC are undeniable, which is why PVC products are in wide use, particularly in the medical field. And it is not easily replaceable for all uses, as noted in a recent study on PVC safety conducted by the European Commission’s Health and Consumer Directorate General,¹⁴⁴ which found: “So far, there is no conclusive scientific evidence that DEHP exposure via medical treatments has harmful effects in humans.”¹⁴⁵ Any evidence of problems relates to high levels dosed to animals, which has very limited application to trace level exposures to humans.

The EPA may want to continue studying phthalates and demanding more research with the hope of finding something scientifically significant, but given the high scrutiny and research already devoted to the chemicals, the agency is unlikely to learn much of anything new. If it is allowed to place phthalates on a

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“concern” list, it will help fuel the unfounded campaign for the demise of a very valuable product—creating a host of new dangers associated with inferior alternatives.

Another example is found in the agency's CAP for bisphenol A,¹⁴⁶ which also proposes the initiation of a rulemaking to add BPA to the TSCA “chemicals of concern list.” Thus far, the EPA’s proposal is pending review at the Office of Management and Budget. The BPA CAP also proposes additional study of BPA and efforts under the EPA’s Design for the Environment program to promote companies to voluntarily reduce the use of BPA.¹⁴⁷

Yet it makes little sense to initiate a new program on BPA as the chemical has already been studied extensively around the world and deemed safe at current public exposure levels by many scientific bodies. Its documented value to society is also extremely high. BPA makes transparent, polycarbonate plastics exceptionally strong and resistant to breakage and to relatively high heat. It is remarkably durable and easily sterilized, making it well suited for reuse and recycling and medical applications. BPA is also used to make resins and coatings that are suitable for application to a wide range of surfaces at a wide range of temperatures. As a result, it helps prevent corrosion and increases product durability. Its application in food packaging—lining aluminum and steel cans for example—reduces food waste and prevents the development of dangerous contamination and pathogens in the food supply, providing a key public safety benefit.

Myriad studies on BPA continue to become available, each with its own claims and limitations.¹⁴⁸ However, even when studies claim to have discovered a new link, it is important to remember that no single study is likely to overturn the complete body of research. In fact, methodological problems and applicability of new studies continue to be an issue with new peer-reviewed research. Scientific panels around the world have reviewed—and continue to review—the complete body of evidence and none report serious concerns about BPA. Instead, they affirm findings of a very low risk. Accordingly, regulatory bodies around the world have determined that the benefits of using BPA to protect our food and perform other functions outweigh any risks.¹⁴⁹

Environmental activists still maintain that BPA must be a problem because humans are exposed to considerable amounts through food and consumer products, which is why it is commonly found in human urine. And some studies show adverse impacts on rodents. However, some rodents cannot metabolize BPA, increasing the opportunity for the substance to have some impacts on rodents’ development and health. The fact that BPA appears in human urine indicates that we do metabolize it quickly, leading little possibility for adverse impacts. A

recent EPA-funded study underscored the fact that BPA is unlikely to produce health problems in humans. It employed volunteers exposed to relatively high levels of BPA in food and measured resulting BPA in urine. The study demonstrated that the substance passed quickly through the human system and never rose above levels shown to cause problems in rodents.¹⁵⁰

The only good reason for the EPA to exert so much effort on BPA appears to be politics. Activist groups have been targeting the chemical for years, arguing that consumers are at grave risk from its use.

The EPA's efforts to demonize BPA by listing as a "chemical of concern" and to encourage its phase-out are dangerous. Elimination of BPA in food packaging poses particularly serious problems because there are no good alternatives for those uses. Packaging manufactures have been trying to remove BPA from their products because of public pressure, but they are having a very difficult time finding safer alternatives. One industry representative told *The Washington Post*, "We don't have a safe, effective alternative, and that's an unhappy place to be ... No one wants to talk about that."¹⁵¹ The EPA should not contribute to political pressures that lead to the removal of BPA products given the serious risks associated with arbitrarily removing valuable medical tools, greater risks from E-coli or simply the risk of broken glass to children should plastic cups and bottles be replaced with "BPA-Free" glass.

Identifying Priority Chemicals for Review and Assessment. Under another initiative of the EPA's Chemical Management Program, the EPA has begun a process to develop a list of "priority" regulatory targets. Unlike the targets it listed under the CAP program, which the EPA appears to have picked out of thin air, the agency has begun an outreach program to industry, nonprofit organizations, and other private parties interested in providing input on which chemicals should become priority for future research and regulation. According to the agency website, "EPA's goal is to identify priority chemicals for near-term evaluation, not to screen and prioritize the entire TSCA Inventory of approximately 84,000 chemicals." The agency held a webinar during which it received comments on the general concept on September 14, 2011, and it has posted some comments it received on regulations.gov.¹⁵² What is currently unclear as to what direction the EPA will take this program in the future.

Other Initiatives. In addition, the EPA has embarked on several other areas related to data collection and dissemination, including efforts to collect more data, particularly data related to high-volume chemicals that are currently not

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included in the voluntary HPV program. Another program focuses on increasing transparency, which raise a host of issues related to confidential business secrets. These are important issues that deserve mentioning, but they fall outside the scope of this paper and should be explored elsewhere.

Conclusion

Whenever lawmakers, industry executives, or anyone who favors free enterprise and innovation hear the call for “TSCA modernization,” they should ask themselves what that really means and whether it is desirable. TSCA may not be the most “modern” environmental law, but it does at least call on the Environmental Protection Agency to apply some critically important considerations before regulating, such as scientifically sound justifications, demonstration that the regulation will provide real benefits, and assurance that the rule itself will not cause more harm than good. Modernization involves eliminating these standards, which hold regulators accountable for their actions, allowing them to regulate in an arbitrary fashion, regardless of the consequences.

The justifications for such “modernization” are not particularly compelling upon close examination. The idea that the law is a failure because it has not produced enough regulations, for example, falls flat considering that the risks of the chemicals TSCA regulates are extremely low. In fact, there is no evidence that TSCA’s risk-based standards prevent the agency from protecting public health. New mandates demanding that companies produce more data are highly unlikely to demonstrate anything different. In fact, the chemicals which the EPA and environmentalists would like to condemn with “new data” have already been studied extensively by private companies, government agencies, and research bodies around the world. And the EPA is even less likely to discover damning information regarding chemicals that have been used for decades without indication of adverse health concerns. Instead, mandates for additional study will simply divert research dollars away from more valuable research and development efforts.

TSCA’s actual failures stem from the cases where the EPA has succeeded in taking regulatory actions under the law. As demonstrated in this paper, the EPA has been able to use the law to impose some needless regulations related to lead-based paint, PCBs, dioxin, and other substances.

Obama administration efforts to revitalize the law indicate that—even without congressional reform actions—the EPA can use the law to impose a host of new regulations as well as make symbolic statements about chemicals to adversely impact their use in the U.S. marketplace. Modernization will most

likely empower the agency to take these programs in an even more arbitrary and capricious direction, undermining freedom, innovation, and economic growth in exchange for no measurable public health benefits.

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