

TSCA Reform: Building a Program That Can Work

by Mark A. Greenwood

Mark A. Greenwood is a partner in the Washington, D.C., office of Ropes & Gray LLP.

Editors' Summary:

The time for TSCA reform is basically now or never. The emerging framework of chemical management from other countries and U.S. states may or may not need to be steered in a new direction or aligned in a more systematic and coherent way by federal legislation. At some point, the policies and practice of the emerging chemical management system will settle into a new equilibrium, perhaps making congressional action a disruptive activity. If, however, there is consensus that federal reform would be beneficial, then it should only proceed with a clear agenda, provision of the necessary resources, establishment of risk-based priorities, protection of the ability to innovate, a balance of burden shifting, avoidance of the new versus existing chemical trap, and by addressing the role of states.

The new Administration and Congress coming to power in 2009 will be asked to address a key strategic issue on chemical management policy that has lingered for many years: whether the Toxic Substances Control Act (TSCA) should be reconsidered and fundamentally changed to assure health and environmental protection. This is an important question not because the law must necessarily be changed. It is important because unless TSCA is changed in the next few years, it is unlikely that it will ever be changed.

TSCA is one of the oldest federal environmental statutes that has never seen substantial reform. When it was passed in 1976, it was considered the cutting edge of environmental law. Yet, as the U.S. Environmental Protection Agency (EPA) struggled to transform the many statutory tools of TSCA into a coherent chemicals management program, policy experts began to criticize aspects of the statute itself. Certainly by the 1980s, TSCA was being characterized as an ineffective law. In the early 1990s, when the courts rejected EPA's comprehensive ban on asbestos, TSCA became widely known as a "broken" statute. Periodically various congressional committees have held hearings to discuss TSCA reform, but none of these efforts produced any substantial result.

In the long period during which Congress contemplated, but did not pursue, changes to TSCA, EPA was able to develop elements of a chemical management program that proved quite effective and became a model for the rest of the world. In particular, many countries borrowed the idea of establishing an inventory of existing chemicals and a parallel program to screen, and regulate as needed, new chemicals entering commerce. EPA also provided international leadership on the idea of developing a base set of testing requirements for high production volume chemicals that would then serve as the starting point for further testing and possible risk management. EPA implemented specific statutory mandates to regulate chemicals like polychlorinated biphenyls (PCBs), lead, and asbestos, again establishing precedents that were adopted by other countries.

In the 21st century, however, both TSCA the statute and TSCA the program lost their leadership position. New actors, bringing new approaches and greater resolve to the issues, have stepped forward and created a more diverse and "multipolar" framework for global chemical management. Perhaps the most obvious of these new leaders is the European Union, which enacted and is now implementing the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) program. In addition, a series of international agreements and accompanying international organizations address key aspects of chemical management. Global commerce in chemicals is also increasingly affected by the health and environmental policies in major Asian countries.

Closer to home, Canada's Chemical Management Plan represents the most ambitious chemical management program

in North America.¹ In addition, a variety of state and local governments are increasingly addressing chemical management issues, usually from the perspective of consumer product safety, that had historically been matters for the federal government to resolve. These measures have taken a variety of forms, including bans (e.g., methyl tertiary butyl ether (MTBE), phthalates), labeling (e.g., California's Proposition 65), and planning programs (e.g., Massachusetts toxic use reduction program).

These programs have been developed, refined, and supported by various governments. They have often drawn wide support from the nongovernmental organization (NGO) community. The business community has in many cases been a collaborator in the development and implementation of these programs. Even where the business community has strongly opposed one of these programs, as it did with the REACH legislation, once the program was established, companies have developed pragmatic strategies to comply with these programs and to work with regulatory agencies to address implementation issues.

In short, what has developed over the last several years is the outline of a framework for chemical management at both a global and regional level that can operate without a comprehensive national chemical management statute or program in the United States. Policy leadership can, in fact, come from Boston, Geneva, Helsinki, Ottawa, and Sacramento. Certainly, this network of policies and institutions is not an entirely consistent or predictable program, and at times is highly dysfunctional from any perspective. At the same time, there are signs that these various chemical management initiatives are beginning to establish connections, both in matters of policy and data-sharing. Perhaps more importantly, the players who must make these policies and programs work are adapting to this new political order, finding ways to achieve health and environmental protection in as predictable and cost-effective manner as possible.

Thus the real issue facing the new Administration and Congress is not whether TSCA can be improved. The question is whether the emerging framework of chemical management across the country and the world needs to be steered in a new direction or aligned in a more systematic and coherent way. Unless there is consensus around that question, there is no compelling need to revise TSCA. The practical window for resolving this question is limited. At some point, the policies and practice of the emerging multipolar chemical management system will settle into a new equilibrium, making congressional action on TSCA reform a less necessary and perhaps even a disruptive activity.

It should be noted that the new Administration will need to address early in its tenure whether EPA's Office of Pollution Prevention and Toxics (OPPT) is on the right track with its Chemical Assessment and Management Program (ChAMP), an ambitious effort by the Bush Administration to assess and

address the hazards and risks of over 6,000 chemicals by the end of 2012. EPA has begun the daunting task of sorting through this long list of chemicals and has issued a series of risk-based priority documents that offer screening-level assessments of the risk of specific chemicals accompanied by general recommendations for additional data needs.

The new Administration will need to determine whether this fledgling effort offers an answer to the larger question noted above and thus should be the centerpiece of the Administration's strategy for chemical management issues. As part of this review, it will be important to consider how ChAMP will address risk management. Understandably EPA's initial efforts under ChAMP have focused on developing methodologies for categorizing chemicals and assessing risk. To be credible, however, a national chemical program must have guiding principles, effective legal authorities, and the capabilities to take risk management action.

I. Factors to Consider for a New TSCA Statute

If the new Congress or Administration decides to take on the task of establishing a new national program for chemical management, it will face several challenges. To avoid many of the problems of the past, it is most important to recognize that a new statute must provide the blueprint for a government program that defines a mission, sets an agenda and provides the tools for effective implementation. This would seem an obvious point. Yet, the history of TSCA reflects a remarkable inability to address those core issues. To assist the potential designers of a new chemical management law, this Article identifies several key issues that will need attention.

A. Define a Clear Agenda

The original TSCA enacted by Congress in 1976 gave EPA a range of statutory authorities to collect information, mandate chemical testing, and impose a broad spectrum of risk management actions. The statute did not, however, provide clear direction on how to use those authorities. EPA knew that it had to screen new chemicals and to regulate PCBs—two tasks that it took on with diligence and commitment. Initially, EPA felt that the ability to craft its own agenda, particularly for existing chemicals, was TSCA's greatest strength.

In fact, the absence of an agenda became the curse of TSCA. It was the statute with the powers to do many things but the mandate to do very little. Some people, including some EPA employees, have referred to TSCA as the "solution in search of a problem" statute. In contrast, the other major environmental statutes were organized around clear agendas that have remained consistent over time, sometimes defined by statute, by court orders, or by salient environmental incidents. The TSCA program did not have such a well-defined long-term agenda and thus suffered by comparison. As a practical matter, the program had difficulty competing for resources with other EPA programs that could argue that their activities addressed clear national mandates. In addition, the TSCA

1. After screening approximately 23,000 chemicals for characteristics of toxicity, persistence, and bioaccumulation, Canada has identified a set of several hundred so-called challenge chemicals that will be the subject of further information collection, risk assessment, and risk management actions, through a series of collaborative and regulatory actions.

program became subject to the variable agendas of successive sets of EPA leaders who did not stay in office long enough to define the program successfully to the Congress, the public, and EPA employees.

Thus, the first among all issues to be addressed in devising a new statute is to define an agenda. All things flow from this decision. It is the key to determining what parts of the statute are and are not broken. It would be foolish, for example, to add further tools to the TSCA arsenal unless one can say how the new authorities will contribute to the agenda. An agenda is also central to the politics of enacting a new statute. It is not easy in these times, with a crowded policy agenda facing the new Congress, to enact any environmental statute. The need for a new law must be compelling; stakeholders need an agenda that they can support.

Beyond the immediate task of enacting a statute, a clear agenda is also essential to the creation of an effective environmental program after enactment. Government programs addressing complex environmental programs are long-term endeavors. The formulation of policy, particularly when rule-making is needed, and the conduct of effective implementation activities require a sustained effort. A clear agenda permits the environmental regulatory agency to complete its program activities, engage important stakeholders, and develop the necessary expertise, commitment, and passion among its staff to make the program work.

B. Provide the Necessary Resources

In the consideration of new environmental statutes, it is fairly common for members of Congress to focus on the policies, authorities, and regulatory actions that EPA should take, leaving to another day questions about appropriations for the new program. In the case of a new TSCA, this would be a major mistake.

The simple fact is that the OPPT, the implementer of the TSCA program, is one of the most underfunded programs in all of EPA. The Agency's programs for regulation of products have always been much smaller than the air, water, and waste programs that regulate facilities. More specifically, the resource allocation to regulation of industrial products has remained essentially stagnant for a decade.

In 1999, the TSCA program operated on a budget of approximately \$30 million, supported by a staff of approximately 270 people.² In 2008, the OPPT budget for TSCA activity was approximately \$50 million. Roughly 28% of the increase over the last 10 years reflected cost of living increases for staff compensation. The rest is represented by increases in the 2000 budget for the high production volume program and a small amount of homeland security funding that EPA, among many agencies, received in the wake of the September 11, 2001, attack. Importantly, the number of people support-

ing the program in 2008 remains at the 270 level, unchanged in almost a decade.

While the TSCA resource base has stagnated, its sister program for regulation of pesticides has grown substantially over the last several years. In 2008, the pesticide regulatory program operated on a budget of approximately \$160 million, supported by a staff of over 900 people.³ These budget figures are useful points of comparison to consider because some of the legislative proposals for TSCA reform draw heavily from the policies and the program design of the pesticide program.

In the last few years, there have been calls for EPA to establish a robust program for the oversight of all new nanotechnology products entering commerce or to come up with an American equivalent to REACH in Europe. Whatever the merits of these proposals, the simple truth is that OPPT simply does not have the resource base to implement programs at that scale. A new national program for chemical management is not an exercise worth undertaking unless the Congress addresses, in parallel to its policy deliberations, a thorough look at the resource needs of EPA.

C. Establish Risk-Based Priorities

The universe of chemicals falling under the jurisdiction of TSCA is very large. While the TSCA Inventory, which includes the names of over 83,000 chemicals, is not a realistic profile of the number of chemicals in commerce, EPA has identified a universe of 7,500 chemicals in production above 25,000 pounds. Of equal significance, the range of uses for TSCA chemicals is as diverse as our economy, making it difficult to evaluate and address all potential exposures to the TSCA chemicals.

It is important to keep the size of this universe in mind when designing a program. For example, some proposals for reforming TSCA offered over the last several years have tried to borrow from the regulatory framework for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). That program requires EPA to issue licenses for individual pesticide products and to engage in re-registration, over a 15-year period, of all existing pesticide products.

The universe of pesticides for purposes of EPA's re-registration work has been organized around a set of just over 700 pesticide cases that are based on the active ingredients used in these products. Moreover, the range of uses and exposures considered in the FIFRA world is substantially smaller than what can occur in the TSCA world. In addition, as noted above, the EPA pesticide program has a larger resource base than the Agency's TSCA program. In short, EPA's pesticide program is a much larger enterprise overseeing a much smaller universe of chemicals and potential exposures. The scale of the TSCA universe does not easily lend itself to a FIFRA model.

It is unrealistic to expect a new TSCA program to review all chemicals under the statute's jurisdiction. The agenda for the program must establish priorities, which should be grounded in risk-based principles. There are many legitimate

2. These specific resource figures, which are drawn from EPA budget information, reflect resource allocations to EPA's "core TSCA," PCB, and asbestos programs. These numbers do not include resources for the OPPT's lead programs and pollution prevention programs, which are less transferable to TSCA regulatory activity. The staffing numbers come from budgetary full-time equivalent (FTE) staffing allocations to the OPPT.

3. This figure does not include approximately \$20 million that is allocated to grants and scientific research in support of the pesticide program.

bases for establishing priorities, but the following factors should be considered.

The existing TSCA Inventory of chemicals is organized around a system of chemical identification nomenclature that is administered by the Chemical Abstract Service (CAS). Individual chemical substances are assigned CAS numbers that help distinguish chemicals with differing molecular structures. Unfortunately many of the differences in chemical structure among similar chemicals represent distinctions without a difference when it comes to questions of risk. As a result, the CAS-based universe of existing TSCA chemicals does not provide a useful tool for identifying priorities. As a point of reference, the lists of chemicals that define the agendas of EPA's other major regulatory programs typically contain several hundred substances or chemical categories. No other program attempts to review or address a chemical list as large as the TSCA universe of distinct CAS-named substances.

Thus it would be important for a new TSCA to define, or call on EPA to define, a finite list of chemicals or chemical categories that warrant attention because they present a significant risk potential. The concept that EPA should engage in effective risk assessment and risk management of the whole TSCA chemical universe may seem appealing to some, but it is a fundamentally impractical agenda that will not succeed. An agenda of several hundred priority chemicals begins to enter the world of possibility, based on the experience of other EPA programs.

A key principle that should be considered in any priority scheme is the potential for exposure. There are several factors that can be used to address the exposure dimension of risk. In the case of REACH and ChAMP, the regulatory framework uses production volume as a surrogate for potential exposure. While production volume is certainly a legitimate factor, it can sometimes steer a program toward chemicals of low-risk potential. For example, there are several high production volume chemicals that are produced as intermediates in chemical processes. In many cases, these chemicals only exist as distinct substances for a short time and do not leave the site where they were produced. They are often found in highly controlled processes presenting limited exposure potential that is well understood and well managed.

In contrast, there are other chemicals, with smaller production volumes, that may be used in highly dispersive applications that present the potential for widespread public exposure. The classic example of this is a chemical found in a wide array of consumer products that may readily enter the human body. Logically, such chemicals should receive closer scrutiny than higher volume, site-limited intermediates. Thus, factors other than production volume alone are needed to establish a priority agenda that is responsive to public concerns.

D. Protect the Ability to Innovate

The importance of technological innovation for this country's future cannot be overstated. It is essential to the success of our economy. Of equal importance, technological innovation plays a key role in addressing a broad spectrum of public issues

concerned with environmental protection, sustainable energy, national security, public health, food supply, and poverty.

Chemical management policies are necessarily aimed at improving how chemicals are manufactured, used, distributed, and disposed. It is inevitable that such policies shape the course of technological innovation. Clearly the primary goal of any new national chemical management program must be protection of public health and the environment. But within that framework, it is also essential for government policymakers to weigh how that program will affect the ability of our society to design and implement technologies that can improve our standard of living and help us address other essential national goals. Interestingly, this need to align health and environmental protection with the ability to innovate is a central tenet of the existing TSCA, as articulated in §2(b) of the statute:

It is the policy of the United States that —

....

(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health of the environment.

Most Americans would agree that a national chemical management policy should be aimed at aligning health and environmental protection with technological progress, a principle that is the linchpin of modern concepts of green design, green chemistry, green energy, and green engineering. In some chemical policy contexts, however, the pursuit of protection goals and innovation goals has been seen as representing a fundamental conflict. This perceived tension is not actually an inevitable outcome, and the designers of new national chemical policy should look for every opportunity to align these goals.

To do this, it is best to avoid elaborate philosophical discussions of policy concepts and focus on the pragmatic aspect of how chemicals are actually produced, distributed, and used in commerce. In the universe of industries touched by TSCA, which is quite diverse, there are big differences in the degree of technological change. For some companies, process changes or adjustments of the ingredients or reactants in a process are special events that do not occur very often. In other companies that operate on the frontiers of technology, such changes are fairly routine events that occur on an ongoing basis. A government oversight system that tried to examine each such change would clearly impede innovation.

Such an oversight system would also be an unworkable government program. A government agency trying to provide such oversight would grind to a halt with an overwhelming workload. The agency would also risk being diverted from other situations that carried more serious implications for public health, since many of the incremental changes in chemical

manufacturing, processing, and use do not change the risk profile of final products or the workplace in fundamental ways.

For the designers of a national chemicals program, there are two general strategies for achieving the right balance: (1) establish good practices of general applicability that improve chemical management across the board; and (2) define appropriate triggers for government investigation and review of private-sector action. Examples in the first category could include hazard assessment obligations (e.g., testing or literature reviews) that attach to the marketing of a product for certain uses or improved hazard communication obligations (e.g., enhancement of current Material Safety Data Sheets that routinely accompany chemical products.) In the second category, there should be clear and transparent criteria that define when a chemical warrants a closer look. These triggers for government oversight should be risk-based criteria, based on hazard or exposure factors.

It would also be useful to define conditions under which government oversight is not needed, both to create incentives for good practice and to conserve the resources of government agencies for more pressing matters. While there are several approaches that could be considered, the following are illustrative examples:

- EPA could establish exposure-based “off-ramps” from chemical-specific oversight, where a set of exposure-based controls in the workplace and the absence of significant levels of the chemical in end-use products, e.g., for a process catalyst, would assure protection. The example of a high-technology “clean room” environment, where delicate production processes must be separated from human contact to assure success of the manufacturing process, may be a useful example of this approach.
- Certain categories of new chemicals reviewed under TSCA go through a fairly formulaic review, based on past experience with similar chemicals. Increasingly, EPA has been able to translate the elements of its review for such chemicals into analytical software tools. In such cases, it may be possible for companies to employ those tools and provide legally enforceable certifications of compliance with EPA safety benchmarks for a chemical, rather than submit a separate notice to EPA for review of each such chemical.

E. Balance Burden Shifting and Reliance on EPA Action

The premise behind the original TSCA was that EPA would be empowered with many statutory tools to allow it to regulate chemicals when needed. As the Agency struggled to develop an effective national program, efforts to reform TSCA frequently focused on what was seen as the stifling “burden of proof” that EPA faced to regulate chemicals. Over the years, there have been several proposals characterized as efforts to shift the burden of proof to chemical manufacturers to prove the safety of their products.

To some extent, this is a simplistic definition of what has ailed EPA’s TSCA program. The argument can certainly be made that EPA’s §6 authority to impose controls on existing chemicals has been stymied by court interpretations of EPA’s statutory burden, as was evidenced in the court decision on the Agency’s asbestos ban.⁴ In contrast, however, the courts have interpreted EPA’s authority to impose testing requirements under §4 of TSCA quite broadly.⁵ Thus, the statutory obligations facing EPA for the enactment of rules do not offer a complete explanation for what has caused the TSCA program to accomplish less than expected.

Nevertheless, shifting the burden of proof will be a core element of various proposals for TSCA reform. In considering these proposals, Congress will need to examine carefully the specifics of what is meant by a “burden-shifting” proposal because very different policies have been given that label. Some are workable and some are not. As a general matter, at least three different forms of burden shifting have been suggested:

- *Ban Unless Proven Safe*—The most profound application of the burden-shifting principle is that no current or future chemical substance should be permitted in commerce unless its manufacturer has proved, based on a comprehensive set of toxicity and exposure tests, that the chemical is safe for all of its intended uses. Given the array of distinct chemical substances used in our society, the scale of testing that would be required to satisfy that test, along with the demands on government to review and reach a conclusion on each chemical, would be monumental. The costs and time delay for industry and government to accomplish this task would be overwhelming and there would be social implications, e.g., the animal welfare implications of that scale of testing, which would not be acceptable to many people. In short, this version is really not a practical approach.
- *Approve All Uses for Hazardous Chemicals*—This version of burden shifting involves identification of a set of chemicals that carry significant hazard concerns followed by an industry obligation to seek approval for each use of each chemical. During the approval process, industry would have to provide sufficient information to demonstrate the safety of the chemical for its intended uses. This is essentially the approach embodied in EPA’s pesticide program, which registers pesticide products for particular uses after a review of the aggregate impact of the pesticide on health and the environment. As noted earlier, this model has worked for the smaller universe of regulated pesticides but may not be viable for the full universe of TSCA chemicals. The REACH authorization process anticipates reviewing and approving individual uses for all “substances of very high concern.” While that universe of chemicals has not yet been defined,

4. *Corrosion-Proof Fittings, Inc. v. EPA*, 947 F.2d 1201, 22 ELR 20304 (D.C. Cir. 1991).

5. *Chemical Manufacturers Ass’n v. EPA*, 859 F.2d 977, 19 ELR 20001 (D.C. Cir. 1988).

estimates of the potential size of that universe raise questions about whether this approach will turn out to be workable in REACH. As a general principle, the key consideration in this version of the burden-shifting concept is whether the universe of chemicals to be reviewed is reasonable enough to allow an agency to engage in the high level of analysis and case-by-case transactions that are required.

- *Tiered Information Obligations*—In this version of burden shifting, industry's obligations to generate and submit information to government (and the public) increase automatically based on certain triggers. Perhaps the simplest example of this model is the expectation that additional toxicity testing requirements for chemicals are triggered when their expected production volume increases. These obligations are built into the overall regulatory framework and do not call for separate regulatory actions for each chemical. The obligations can be very specific (e.g., a particular animal test with a known protocol) or more generalized (e.g., an assessment of the exposure potential for specific chemical uses). This type of burden shifting for information collection and submission has been a central feature of the REACH program, and thus is probably the most commonly understood version of what is meant by burden shifting in the context of TSCA. While there are many issues about what kinds of informational obligations should be triggered by factors like production volume, use pattern, hazard information and other factors, this approach can be accomplished on a larger scale than the other two versions of the burden-shifting concept.

A theme that runs through these proposals for burden shifting is a desire to make chemical control policies more self-implementing, removing the need for EPA to make case-by-case decisions as contemplated by the original TSCA. While it is certainly true that self-implementing requirements will yield specific results, Congress should also recognize that EPA must have adequate authority to take effective action and to modify counterproductive requirements. No set of self-implementing requirements that evolves from the political process of enacting a new statute will be right for all situations. Thus, a thorough review of EPA's existing legal authorities under TSCA should be part of the legislative process.

As an example, Congress should make sure that EPA has the ability to collect information quickly in response to an emerging chemical risk issue. Under the current statute, EPA has tended to rely on its rulemaking authorities under §8 to collect information when it has concerns about a chemical. Despite several innovative efforts to make those authorities more streamlined, EPA has had difficulty collecting information quickly under §8. In contrast, EPA has virtually ignored its subpoena power under §11(c) that allows the Agency to issue an administrative order requiring submission of information, bypassing the ponderous process of rulemaking. Congress should examine why EPA has chosen what appears to be the less efficient path for collecting information about

chemicals and determine whether clarification of the Agency's administrative order authority is needed.

Similarly, Congress may want to consider whether a similar administrative order authority would be valuable to require the creation of new information, e.g., chemical testing, about chemicals. Such an authority, which could be similar to §3(c)(2) (B) of FIFRA, might be a valuable tool for collecting targeted hazard or exposure information. There may, however, be substantial opposition to such an authority if it is too open-ended. Thus, Congress may need to limit the scope of this authority to certain categories of tests or even an overall cost cap.

Finally, Congress will almost certainly be asked to give EPA authority to waive or modify any self-implementing information collection or other requirements that might be placed in the statute. The conditions triggering this authority could involve emergency situations, small business impacts, or unanticipated counterproductive effects. While there will be significant debate about the need for and the scope of such an authority, some form of a waiver or modification authority is a likely component of any new statute with the potential impact of a new TSCA.

F. Avoid the New Versus Existing Trap

TSCA is old and thus it embodies old ideas. During the heyday of new environmental legislation in the 1970s, Congress was enamored with the idea that EPA should establish a separate set of requirements for new and existing facilities and new and existing products. The premises underlying this distinction certainly were understandable. It was assumed that new facilities and products were in a better position to meet a higher standard of environmental protection. New industrial plants could integrate new pollution control into their operations. New products could be designed to avoid undesirable characteristics. In addition, Congress was also making a basic political judgment that it would be easier for EPA to say no to new commercial activities than to existing activities where substantial economic investments had been made.

The downsides of this approach, however, have been documented for over 30 years in many environmental regulatory contexts. In the context of TSCA, the chemical industry has consistently complained about the "new chemical bias" in the program. New chemicals face careful scrutiny, which may lead to additional testing requirements or environmental controls. Meanwhile the existing chemicals that these new chemicals may replace have rarely gone through the same kind of assessment. Overall, this means that the new versus existing distinction is placing more regulatory burdens on innovative materials that have met EPA criteria for safety.

Some have argued that the solution to this problem is that EPA should establish an existing chemical program that applies the same level of analytical rigor and risk management policies as the new chemical program. At various times, EPA has attempted to do this, but it continually ran into two overwhelming problems: (1) the sheer size of the existing chemical universe; and (2) the understandably different perspective

that industry has about existing chemicals that may underlie a series of technological and economic investments.

There is another fundamental problem inherent in a regulatory program built around a distinction between things new and existing. Such a regulatory structure inevitably causes participants in the regulatory debate to fight about the wrong issues. Instead of deliberations about what are the right policies to guide risk assessment or risk management, the participants find themselves quibbling over arcane questions about what it means to be new. Certainly anybody who has participated in the Clean Air Act debate about new source review (NSR) for electrical utilities has experienced the mind-numbing and ultimately unproductive discussion of whether the replacement of boiler equipment is a major modification (triggering NSR) or is routine maintenance (which does not trigger such review).

In the context of TSCA, the latest version of the new versus existing discussion is the consideration of whether all nanomaterials are new chemicals that should be the subject of pre-manufacture review. At a larger policy level, there is fairly broad consensus that some form of oversight program for nanomaterials is prudent to assure health and environmental protection and to help build public confidence in this promising new wave of material science. Yet, once the TSCA new versus existing issue comes up, the various players in the nanotechnology policy field square off on age-old debates.

EPA has generally taken the position that a chemical is not new if it has the same molecular identity as another chemical currently on the TSCA Inventory. The Agency does not treat variations in the physical structure of a substance with a common molecular identity as creating new substances. Since nanomaterials are generally engineered substances that differ from existing chemicals only by their physical structure, they do not fall within the TSCA new chemical program according to EPA.⁶ Industry groups have supported this view, while NGOs have opposed it. It is a debate that has tended to sidetrack efforts to work collaboratively on a rational oversight program for nanomaterials.

For Congress, the best approach for addressing the age-old new versus existing chemical issue is to remove it from the discussion. To develop a better approach for managing chemicals going forward, Congress should develop triggers for government review of chemicals that have some rational relationship to potential risk. The new versus existing distinction, like the review of chemicals by CAS number concept discussed earlier in this Article, takes regulatory agencies away from the main business at hand—identifying and addressing chemical risk in society.

This does not mean that government should be expected to prove that a risk exists before it is allowed to review a chemical for potential risk. There are reasonable surrogates for potential risk that are far superior to a new versus existing chemical

distinction. For example, the structure of REACH is based on the anticipated volume of a chemical being introduced into commerce, which is reasonable first-level estimate of potential exposure. Further refinement of such concepts can and should be developed.

G. Address the State Role

When TSCA was enacted in 1976, it was politically possible to design a chemical management law that made only passing reference to the states. Such an approach is neither sound politics nor reasonable policy in the present day. State health and environmental programs have grown substantially over time, and the states have developed a series of chemical management programs, many of which operate at the cutting edge of policy.

If Congress undertakes TSCA reform, there are at least three aspects of the federal-state relationship that it should consider. The current language of TSCA has created constraints on the sharing of chemical information that qualifies as private-sector confidential business information between federal and state agencies. As long as state agencies can assure that such information will be protected from disclosure to the same extent as it would be in the hands of federal agencies, there is no reason to prevent interagency exchanges of information. This is one area where there is fairly broad support across the political spectrum for statutory change.

Congress should also examine how EPA and state agencies should structure their role as co-regulators of chemicals that become the subject of risk management actions under TSCA. Virtually every other EPA program has crafted a federal-state partnership to implement federal requirements. Consideration of how such a partnership should work under TSCA, including the need for state program funding, is an important issue for Congress to address.

Finally, as noted elsewhere, it is inevitable that a new national chemical program is not going to address every chemical management that could arise. There will be situations where the states will want to take action on their own, as they have for several years. The states retain the presumptive right to address chemical management matters unless federal law operates to preempt state action in certain areas.

It is highly likely that Congress will be asked to address the question of whether a new TSCA should preempt state statutes and common law. Specifically, there will be a question about whether existing §18 of TSCA, which addresses preemption, should be repealed, retained, or modified. Since preemption debates tend to draw advocates with strongly held views, this topic could be one of the more contentious aspects of the legislative debate.

In addressing these issues, Congress should recognize that there are two differing policy frameworks that have characterized past debates on preemption. Some have argued for federal preemption where the federal government has occupied the field for a certain set of regulatory issues. Under this approach, federal agencies should be the only governmental regulator, even where those agencies have not yet taken action

6. In actuality EPA's distinction between physical structure and molecular identity in the nanotechnology context has been somewhat nuanced. For example, EPA takes the view that various allotropes of carbon are distinct chemicals, which brings most carbon nanotubes into the TSCA new chemical program. The distinctions among allotropes are primarily physical, because all of these allotropes are carbon from a chemical identity perspective.

or even addressed the regulatory issues. The rationale for such an approach is that there is a national interest that is so paramount that consistent action by federal agencies is the only appropriate response to the issues of concern. Certainly this approach is the most controversial.

The second framework involves so-called conflict preemption. The presumed scenario underlying this approach is that the federal government has imposed a requirement and a state has taken action that directly conflicts with the federal requirement. A simple example would be a state action prohibiting a company from complying with a federal requirement, forcing the company to violate either federal or state law. While such scenarios actually do not arise as often as they are sometimes claimed, the rationale for this type of preemption of state law is the most compelling. With either form of preemption, however, there will be controversy, and Congress would be best served by discussion of tangible examples of situations that raise preemption questions.

II. Conclusion

There is a reason that TSCA has remained essentially unchanged for over 30 years. Developing a better national chemical program than we have today is an extremely challenging task. If the new Congress and Administration decide to take on this challenge, they will need to engage in a sustained and thoughtful effort, which may well take more than one Congress to complete. If they are able to address effectively the key issues identified in this Article, however, they will be able to do more than enact a statute. They will be able to design a workable chemical management program that after enactment, can yield enhanced health and environmental protection for the American people.