Point/Counterpoint

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The Future Of U.S. Chemical Regulation

Two views on whether current law overseeing commercial chemicals in the U.S. is tough enough

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The Environmental Protection Agency oversees commercial chemicals through a statute signed into law by President Gerald Ford in 1976, the Toxic Substances Control Act (TSCA). That law has remained substantially unchanged for 30 years.

TSCA established a system for evaluating new industrial compounds for health and environmental effects before they enter the U.S. market. The statute also grants EPA the authority to require chemical manufacturers to conduct toxicity tests on any substance already on the market.

Peter Cutts Photogrpahy (Both)

Face-Off
Walls (left), a managing director at ACC, contends that the structure currently in place for chemical regulation is strong, while Tickner, an assistant professor at the University of Massachusetts, Lowell, argues that EPA's ability to implement these controls is limited.

In addition, the law gives the agency the authority to control chemicals that pose a risk to health or the environment. This includes banning the production or use of chemicals. EPA used this authority in 1989 to ban products made with asbestos, a known human carcinogen. But a federal court in 1991 overturned the ban, saying that EPA failed to consider less economically burdensome regulatory alternatives. Since that court decision, the agency has not banned the use of any chemicals.

The American Chemistry Council (ACC), whose members include major chemical manufacturers, believes TSCA remains a solidly written statute that provides a great deal of authority to EPA for protecting health and the environment. This law, the trade group says, promotes innovation and has strengthened the global position of the U.S. chemical industry.

Others say TSCA has serious limitations and needs an overhaul. They point to the European Union's new legislation on the Registration, Evaluation & Authorization of Chemicals (REACH) as a new model for regulating commercial substances. REACH will establish a control system broader than TSCA's requirements, mandating that chemical makers provide toxicity data on the substances they produce, including ones that have been on the market for decades.

Michael P. Walls, managing director for regulatory and technical affairs at ACC, has actively spoken out against REACH. He writes about the strengths of TSCA, and he argues that it remains a solid authority for addressing new challenges such as products of nanotechnology.

Joel Tickner is assistant professor in the department of community health and sustainability at the University of Massachusetts, Lowell, and was a member of C&EN's advisory board from 2004 to 2006. He argues that TSCA has a number of weaknesses and calls for talks among chemical makers, users, states, and environmental advocates on how to address those limitations.

Walls Point

The business of chemistry in the U.S. is on the cutting edge of technological innovation and progress. Its products provide significant benefits that save lives, improve health, protect our drinking water and food supply, and provide well-paying jobs around the country.

The business of chemistry is also one of the most pervasively regulated industries in the country, and rightly so. Because if chemicals are not managed safely, they can have significant health and environmental consequences.

Unfortunately, the depth and complexity of the U.S. chemical regulatory system belie the considerable authority granted to EPA and how well health and the environment are protected. Some commentators and public interest organizations have mounted campaigns that trade on that very complexity, distorting the reality of chemical regulation, notably under the Toxic Substances Control Act. The facts demonstrate that the U.S. chemical regulatory system provides important protection for both the environment and the health of Americans.

When TSCA was enacted in 1976, about 63,000 chemicals were "grandfathered" onto the TSCA inventory of chemicals. Since then, all "new" chemicals have been evaluated by EPA (some 25,000) before being placed on the inventory. But the number of chemicals on the inventory (about 87,000) is not equal to the number of chemicals in commerce. Only about 10% of the inventory, about 8,300 chemicals, is in actual commerce in significant amounts. Substances comprising the remaining 90% are either no longer produced, produced in such small volumes that they pose little or no risks, or are polymers or salts, which are also presumed to pose little or no risks.

EPA has been given considerable authority to regulate—even ban—the manufacture, use, and distribution of all chemicals on the TSCA inventory, including the grandfathered chemicals. Manufacturers must provide EPA with health and safety information if asked, they must track health effects on workers and customers, and they must immediately report to EPA any information suggesting that a chemical presents a substantial risk of injury to health or the environment. In addition, EPA can compel manufacturers to provide additional test data when needed by agency scientists to complete a risk profile or to make a sound decision.

Some argue that TSCA has failed because EPA cannot restrict chemical uses, and they point to the failure of EPA to ban asbestos-containing products as proof. That simplistic statement should raise considerable concern, if it were true. The fact is, EPA has restricted the use of thousands of chemicals. The failure to ban asbestos was related to procedural missteps, not the fault of the statute.

Statements alleging a lack of information about chemicals in commerce are often made during TSCA debates. Again, not true. Companies develop a great deal of information on their chemical products. In fact, industry has voluntarily supplied EPA with evaluation data covering more than 95% of all chemicals in commerce today, by volume. In this program, known as the High Production Volume (HPV) Challenge Program, more than 300 sponsoring manufacturers volunteered to provide hazard-screening information on 2,222 HPV chemicals. This information is publicly available at www.epa.gov.

EPA is now completing its screening of the HPV information and prioritizing chemicals for additional in-depth reviews. And EPA is mid-way through its Voluntary Children's Chemical Evaluation Program, a pilot effort to assess chemicals for their potential effects on children.

As science evolves, we learn more about the relationship between chemistry and health, between chemistry and the environment. For example, as the technology of detection improves, we learn more about the presence of chemicals in the environment and even in the human body. While the presence of chemicals in the body is not itself surprising (humans are a product of chemistry, in more ways than one), even the Centers for Disease Control & Prevention caution that the mere presence of a chemical at trace levels (parts per billion or parts per trillion) is not an indication of disease or illness. The toxicity of a chemical relates to its dose or concentration.

Our improved ability to detect chemicals in the human body, however, has currently outstripped our ability to interpret this information in a health risk context. But scientists are engaged in research to understand the meaning of this new biomonitoring information. And if science tells us that specific chemical levels pose a risk to health, EPA's regulatory authority under TSCA (and other statutes) can be used to address these concerns.

TSCA not only protects health and the environment, it also fuels innovation. More new chemical applications are filed in the U.S. than in any other chemical regulatory system, including Japan's and Europe's. One-quarter of all patents filed in the U.S. relate to chemistry, and the industry spends more than $23 billion a year on research and development.

TSCA is not the only federal law that regulates chemicals; more than a dozen other laws also control chemical use in the workplace, in the home, and in specific applications. Together, these laws form a robust regulatory framework that can deal appropriately with future challenges.

All the regulatory authorities in TSCA and the other laws will mean little if they are not effectively implemented. It is incumbent on EPA and other agencies to demonstrate how they are implementing these statutes to protect health and the environment. But the fundamental structure of chemical regulations in the U.S. is strong.

Tickner Point

As a scientist, I am concerned about the buildup of toxic chemicals in our environment and their impacts on human and ecosystem health. Every year, more scientists publish research that finds potentially dangerous industrial chemicals in places most people do not think they should be: in air, water, food, and our own bodies, including the womb. Research increasingly indicates that many chemicals once thought to be safe may actually harm humans and ecosystems.

Chemicals play a critical role in the global economy and our quality of life. The problems that arise with their use, however, indicate a failure of both government policy and design. It is time to update our 30-year-old chemicals policy.

Public surveys indicate that most people believe that the chemicals they buy in everyday products have been thoroughly tested and demonstrated to be safe by industry and government. The truth is that thousands of chemicals in commerce lack basic publicly available toxicological data and are assumed safe until proven dangerous. This situation erodes public confidence in government, industry, and chemistry.

When enacted in 1976, the Toxic Substances Control Act was viewed as a pioneering law, giving EPA broad authority over chemicals. But numerous critiques over the past two decades have demonstrated limitations in EPA's ability to implement TSCA regulations and the need to modernize this law, including:

- Lack of information on chemicals in commerce. TSCA requires industry to submit only limited data on chemical hazard and use. Much of the data, however, are unnecessarily claimed as confidential, thus preventing the public and non-EPA authorities from accessing it.
- Slow and cumbersome chemical-by-chemical risk assessment and management processes. EPA's ability to issue regulations for testing of chemicals or risk management is restricted by the scientific and legal evidence the agency must amass before it can act. This means that while EPA is fulfilling a significant administrative burden for each chemical it seeks to regulate, chemicals of potential concern remain largely unregulated.
- Unequal treatment of "new" and "existing" chemicals. EPA has significant influence and ability to control chemicals before they come to market but not for those already on the market when TSCA was enacted. That category includes substances on the market before 1979, which make up 99% of the volume of chemicals sold today. To restrict a chemical already in commerce, EPA must demonstrate an unreasonable risk, which requires strong toxicological evidence, as well as show that the benefits of regulation outweigh the risks of not regulating and that EPA's chosen restriction is the least burdensome means to reduce risk to acceptable levels. Since a federal appeals court in 1991 struck down EPA's regulation of asbestos for failing to meet this burden, the agency has had neither the resources nor the ambition to apply these regulatory authorities under TSCA. Instead, it has had to rely on voluntary initiatives.

Despite TSCA's limitations, EPA, with its dedicated scientists, has undertaken important efforts to understand chemical risks and stimulate the development of safer chemistry. The agency has developed a comprehensive set of tools to predict chemical fate, exposure, and toxicity on the basis of chemical structure. EPA uses these tools to review new chemical submissions and encourage industry scientists to understand risks and to identify safer chemical syntheses and products at the design stage.

In cooperation with environmental advocates and the chemical industry, EPA initiated the High Production Volume Challenge Program, a voluntary initiative designed to obtain basic toxicity data on some 2,800 chemicals produced in amounts of more than 1 million lb per year. The agency has been a world leader in stimulating safer design of chemicals and products through its Green Chemistry and Design for Environment initiatives. These initiatives are viewed by industry and environmental advocates alike as innovative and forward-looking.

Although pioneering, these initiatives are, however, highly underfunded and limited in impact.

Limitations of chemicals management efforts are similar throughout the world, but other nations have begun to address them. The European Union last month finalized a broad overhaul of chemicals policies. Called REACH (Registration, Evaluation & Authorization of Chemicals), the legislation will require manufacturers (including producers exporting to Europe) to generate use and toxicological data for chemicals and will authorize controls on substances of concern, such as carcinogens.

Enactment of REACH follows a six-year public dialogue in Europe on chemicals management. Such a dialogue has yet to occur in the U.S.

While European companies and governments are preparing for REACH, the U.S. government and chemical industry aggressively pushed to limit the EU program. Rather than helping industry, this opposition has placed U.S. companies at a competitive disadvantage, without the support and knowledge necessary to innovate and maintain markets in Europe and elsewhere. The ability to meet and surpass European standards is critical, considering that in 2005, U.S. chemical exports to the EU were worth $186 billion, led by California, Texas, New York, and Massachusetts. U.S. opposition to REACH also stifles discussion on reforming U.S. chemicals management, despite an interest in such dialogue by states, environmental advocates, and many users of chemicals.

Thirty years after enactment of TSCA, we know a lot more about chemical hazards, exposures, and chemicals management. We need a modern chemicals policy that responds to the well-recognized limitations of TSCA, is consistent with public expectations about chemical safety, and builds U.S. leadership in areas such as chemicals assessment and green chemistry. Through this effort, the U.S. can be a global leader with vibrant, globally competitive firms leading markets toward a new generation of high-performance, safer chemicals and products.

Walls Counterpoint

The U.S. has made significant progress in addressing concerns about toxic chemicals in the environment. With statutes ranging from TSCA to the Toxics Release Inventory to the Clean Air and Clean Water acts, among others, important reductions have been made in possible exposures to toxic chemicals. For example, potential exposures to lead have been reduced significantly.

That we can now detect more chemicals at trace concentrations in our bodies does not mean that we are being exposed to more chemicals than before. Nor does it mean that chemicals are accumulating in us at a greater rate. It only means we can now measure smaller concentrations than ever before. According to the Centers for Disease Control & Prevention, the fact that a chemical can be found in our bodies doesn't mean it's causing disease. New research is being done to find ways to compare biomonitoring levels to exposure levels that federal agencies have previously determined to be safe. And EPA and other federal agencies have enormous authority under TSCA and other statutes to act to protect public health.

TSCA was crafted by Congress to protect human health and the environment, and it has proven to be a remarkably robust and adaptable tool. Several critiques of the statute warrant a response:

- Information on chemicals. More information on more chemicals becomes available every day. EPA's High Production Volume Information System will be an important tool to access information on 95% of the chemicals in U.S. commerce by volume. Some information on chemicals submitted to EPA is claimed as confidential, which Congress permitted to promote innovation and to protect sensitive commercial property. TSCA, however, requires the agency to disclose that information if it is necessary to protect health and the environment, and it can compel the disclosure if necessary.
- Assessment and management processes. Far from limiting the agency's ability to obtain information on chemicals, TSCA makes EPA's job easier. EPA can compel the conduct of new testing if in the agency's view a substance "may" present an unreasonable risk, and the statute requires no threshold of scientific information to support that view. That is hardly an insurmountable barrier to agency action. EPA also has authority to mandate the submission of certain use and exposure information, as well as existing test data on chemicals.
- Treatment of new and existing chemicals. There are differences in how new and existing chemicals are treated under TSCA. But those differences are evaporating as EPA uses its authority to understand the hazards and risks of existing chemicals. EPA has completed its initial screening of high-production-volume chemicals (again, 95% of the chemicals in U.S. commerce) for further review and assessment. The agency has exercised its TSCA authority to require testing on more than 200 chemicals, and it has required specific information on more than 1,100 others. Over 50,000 health and safety studies have been submitted to EPA, covering a broad range of potential health and ecological effects.

Whatever limitations there may be in implementing TSCA, however, this does not mean that the federal government, or any state government, should blithely adopt the EU's REACH system. REACH will take effect on June 1, and the first regulatory decisions under REACH are some time away. It is untested and unproven. REACH attempts to impose a one-size-fits-all approach to chemical regulation, at a significant cost in government administration and company resources. Only time will tell whether the expensive and highly restrictive system being built in Europe will spur or harm innovation. What we do know is that under the reasoned TSCA approach, the U.S. leads the world in the development and commercialization of new chemical products.

In 2003, in describing REACH, the EU's then-environment commissioner Margot Wallstrom made clear that REACH could very well have negative economic and competitive implications for Europe. She acknowledged that those consequences would be mitigated, however, by the extent to which the EU is successful in establishing REACH as the new international standard for chemical regulation. The EU's

motivation in promoting REACH must be understood in those very fundamental terms.

There is proof of the U.S. industry's competitive edge in the global chemical industry. Registrations of new chemicals in the U.S. outpace those in every other country in the world. U.S. chemical manufacturers are regularly recognized for their new, innovative products and processes in national programs such as EPA's Green Chemistry Initiative. Billions of dollars in energy efficiency savings are attributable to the products of chemistry, complementing the industry's success in reducing fuel and power consumption per unit of output by 46% since 1974 and 18% since 1990 alone.

In short, TSCA is a modern chemicals policy, capable of addressing the issues raised by living in a chemical world. This is a world in which technology constantly evolves, and we find ourselves knowing more and more about smaller and smaller concentrations of chemicals. TSCA is clearly capable of addressing new issues like biomonitoring information and nanotechnology. That's good news, because new information, new technologies, and new products will help protect public health and the environment while maintaining the U.S. chemical industry's competitive lead in the global economy.

Tickner Counterpoint

ACC would like C&EN readers to believe that the "fundamental structure of chemical regulations in the U.S. is strong," that chemicals are thoroughly tested for their human and ecosystem risks, that chemicals accumulating in humans is just a figment of better analytic methods, that the current chemicals safety net is more than adequate, and that today's system is a great generator of innovation.

On the basis of more than a decade of research and work in this field, I disagree. I've worked with chemical-using companies, governments, and other groups that are starving for good chemical safety data and tools and incentives to implement safer chemistry. The chemical industry's lack of transparency is impeding its ability to innovate. Yet, if we can effectively apply our increasing understanding of chemical toxicity, exposure, and green design, I believe we can create a chemicals management system that addresses the problems of the past and sets a course toward global leadership in safer chemicals and products.

ACC paints an inaccurate picture about chemicals management. The exact number of chemicals actually in commerce today is unknown but likely ranges from 8,300 to 82,000. The chemical industry is now developing screening-level toxicity data on only about 2,200 high-production-volume chemicals, but this is insufficient for decision-making. Thousands of chemicals, which may present important risks to health or the environment, continue to lack basic data. Thus, government agencies, chemical users, and the public cannot make informed decisions regarding chemical safety. Data are even sparser on how these chemicals are used and flow through the economy, as well as on potential human exposure to them.

TSCA established strong procedures for reviewing chemicals prior to their manufacture, and EPA often places limits on how these new substances can be used, pending tests. Yet the 99% by volume of chemicals on the market prior to 1980 undergo no mandatory EPA review. From a scientific perspective, chemicals can pose risks regardless of when they were first produced. As ACC notes, companies are not required to test these chemicals, but that doesn't mean that the compounds are safe. EPA requests data on a chemical-by-chemical basis when it can demonstrate a potential unreasonable risk or high exposure. But even if the agency has sufficient information that a substance is dangerous, EPA's ability to regulate is exceptionally limited. Fewer than a dozen existing chemicals have been subject to any EPA restrictions in 30 years.

Review of new chemicals under TSCA arguably supports innovation in the development of safer chemicals in large part as a result of EPA's efforts to provide tools for design and toxicity assessment. However, there is little incentive for widespread diffusion of these new chemicals, given that existing substances can continue to be used with little burden on industry or oversight from government. Further,

government R&D, technical, and market support for diffusion of safer chemicals and products has been minimal at best.

The buildup of industrial chemicals in children should never be viewed as "acceptable" but rather as a failure of design and a responsibility that we must commit to fix. Analytic methods have improved for chemical detection. That is a good, because now we can better comprehend the extent to which humans and ecosystems are contaminated by industrial chemicals. We increasingly understand that exposures to very small doses of chemicals during vulnerable periods of development can result in lifelong impacts. We know little about the implications of the multiple chemical exposures affecting all of us.

Several states and many leading companies acknowledge the limitations of our current regulatory framework for managing chemicals. A growing number of firms espouse the principles of green chemistry and design for environment as guides for their management of chemicals. This trend represents an implicit acknowledgment that chemicals and their use can pose problems and should be safer. Given the lack of proactive federal response to concerns about chemicals management and to international efforts, several states, such as California, Maine, Massachusetts, and Washington, have initiated dialogues about chemicals reform. This development is positive and demonstrates the need for identifying new solutions to chemicals safety on a federal level.

We need a new vision for federal chemicals management based on information rather than ignorance; accepting responsibility rather than abdicating it; adequate government authority and oversight rather than constrained ability to act; and innovative, proactive solutions rather than reaction. A new structure must provide good information on chemical use, hazards, and exposure. It must provide technical and research support and incentives for the development and implementation of safer chemicals and products. It must provide resources the government needs to efficiently act to protect health and ecosystems. And it must aim to reduce the environmental and human burden of chemicals and impacts caused by them.

Our chemical industry and our government risk being marginalized in a global market that is increasingly concerned about the health and environmental implications of industrial substances. It is time for industry and the federal government to acknowledge the benefits of a renewed chemicals management structure. Only then can we begin to map the path toward designing and implementing safer, more sustainable chemistry.

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