Chemical Regulation: Preparing to Address the Challenges Ahead

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Editors' Summary:

There are increasing calls for significant reform of how chemicals are regulated in the United States. The advent of the European Registration, Evaluation, Authorization, and Restriction of Chemicals system, rapid commercialization of nano-enabled products, increased consumer awareness, and proliferation of retailer initiatives have all fundamentally changed the chemical regulatory landscape. In order to navigate this new territory and to make any reforms meaningful, it is vital to understand the implications of both global and domestic chemical management programs, educate congressional staff about chemical management, and identify and agree to common principles upon which any reform efforts should be based.

The environment has enjoyed unprecedented attention as a presidential campaign issue. While climate change, energy, and resource issues dominate, chemical regulation reform is plainly a topic gathering steam. As we approach a new year, a new Administration, and a new Congress, there is much to consider. Issues pertinent to chemical management are complicated, the rhetoric is strident, and areas on which stakeholders agree appear to be few and far between. This Article offers a few thoughts on how best to prepare for effective chemical regulation reform.

I. The Changing Playing Field

Debate over the Toxic Substances Control Act's (TSCA's)[1] strengths and weaknesses is as old as the law itself.[2] What is new is the radically different playing field on which this debate will play out over the next congressional sessions. Several events have changed fundamentally the playing field and are both fueling the momentum that will result in TSCA reform and influencing the content of the change itself.

A. REACH

The European Union's (EU's) newly enacted comprehensive regulation for industrial chemicals is, to use the parlance of the day, a game changer. Adopted in 2006, the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)[3] regulation covers all chemicals, both new and existing, produced in or imported into the EU in quantities above one metric tonne per year and requires that each be registered. While there are certain exemptions for low risk chemicals, the European Chemicals Agency (ECHA), the new agency created to manage and coordinate REACH implementation, expects to register some 30,000 chemicals. A dossier must be prepared and submitted on all chemicals, which will be evaluated against a base set of toxicological data requirements, with ascending levels of data depending upon production volume. For chemicals produced in quantities above 10 metric tonnes, a more extensive chemical safety report is required.

The evaluation component of REACH involves a completeness check for compliance and other related reviews intended

1. 15 U.S.C. §§2601-2692.
2. Several Government Accountability Office (GAO) reports have catalogued TSCA's strengths and weaknesses. *See, e.g.*, U.S. GAO, Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program (2005) (GAO-05-458); U.S. GAO, Chemical Regulation: Actions Are Needed to Improve the Effectiveness of EPA's Chemical Review Program (2006) (GAO-06-1032T). Prominent public interest groups also have long criticized TSCA and have called for chemical reform. *See, e.g.*, Richard A. Denison, Not That Innocent: A Comparative Analysis of Canadian, European Union, and United States Policies on Industrial Chemicals (2007).
3. EC 1907/2006, *available at* http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm.

to promote data-sharing and avoid animal testing. Evaluation yields to the REACH authorization component, generally reserved for substances of very high concern (SVHC), including carcinogens, mutagens, and reproductive toxicants, and persistent, bioaccumulative, or toxic substances, very persistent or very bioaccumulative substances, persistent organic pollutants, and other substances. A core goal of the authorization component is product substitution. Sponsors of an SVHC must present a research plan and/or replacement plan for the substance. Absent viable alternatives, continued applications of the substance are allowed only if a cost-benefit analysis concludes continued use of the substance yields benefits that outweigh any risks.

Several points about REACH merit note here because they raise important questions about TSCA's utility and effectiveness. First, REACH eliminates the distinction between new chemicals and existing chemicals that were first marketed before 1981 and thus essentially not required to satisfy certain testing requirements. Under TSCA, the distinction between "new" and "existing" chemicals has been particularly controversial. As any TSCA practitioner will attest, the distinction can be difficult to discern and has hugely important regulatory consequences. New chemicals are subject to U.S. Environmental Protection Agency (EPA) premarket approval. Existing chemicals need no premarket approval. The debate over new versus existing chemicals has focused most recently under TSCA on whether nanoscale forms of existing conventionally sized chemical substances should be considered new chemicals and thus subject to EPA premarket review and approval.

The wisdom of TSCA's grandfathering of existing chemicals has long been questioned, and TSCA supporters will need to sharpen their advocacy if the distinction between new and existing is to survive. REACH provides a ready model for TSCA reform and offers what some regard as a more rational approach to chemical management. While more recent voluntary initiatives such as the High Production Volume (HPV) Challenge Program and the much newer Chemical Assessment and Management Program (ChAMP) have provided (and in the case of ChAMP will provide) much more information on existing chemicals, it is unclear whether even with these initiatives any serious TSCA reform initiative can or should preserve the new versus existing distinction as it is perceived to be an intrinsic part of what some strongly believe is a failed chemical management program.[4]

Second, REACH places on industry the legal burden of proving chemicals are safe, embedding the precautionary principle in the law itself. By contrast, TSCA places the burden of proving that a chemical substance poses an "unreasonable risk" on the government. Who bears the burden under TSCA of proving that a chemical poses harm has been a sticky issue over the years, and likely will be a key issue in forthcoming chemical reform debates. Despite the bad rap TSCA has earned over the years, under it EPA has considerably more authority to compel information and action in the face of uncertainties regarding risks a chemical may pose than its detractors claim.

It could be that the debate should focus less on shifting legal burdens and more on EPA deploying more consistent, aggressive, and efficient existing TSCA authority. A more probable result, however, is that TSCA reform measures will emulate REACH in this regard. REACH provides an easily available model for reform that many find compelling. Some will argue also that it is good public policy to require the manufacture of a material to demonstrate its safety as a prerequisite to commercialization. Failure to require less is a tough sell, particularly in light of much-cited judicial decisions like *Corrosion Proof Fittings v. U.S. Environmental Protection Agency*,[5] where EPA's regulatory efforts to ban asbestos were rebuffed. Although those most familiar with TSCA are quick to point out that *Corrosion Proof* is more an example of EPA's failed implementation of the statute than an indictment of the statute itself, it simply may not matter given the widespread belief that TSCA has failed in key respects.

Third, REACH is, among other things, a right-to-know/data production tool. Copious amounts of information on the toxicological and ecological effects of chemical substances, use patterns, and related information will be submitted and made widely, publicly, and immediately available. The sheer volume of this information, its ready availability, and the many ways in which it will be interpreted, packaged, and disseminated offer infinite commercial impacts, key among them product and/or use deselection opportunities.

TSCA, on the other hand, is less data production-oriented and less transparent. While new data may be required to be produced under TSCA §4, EPA's success with compelling data production has been checkered. And, although health and safety data cannot be claimed as confidential, much information submitted as part of a premanufacture notification (PMN) can be, and often is, claimed confidential.

The contrast between REACH and TSCA in both regards is stark. REACH's implementation will almost certainly focus renewed concern on TSCA's perceived limitations in compelling data and limiting claims of confidentiality, and TSCA reform measures can be expected to address both perceived limitations.

B. Rapid Commercialization of Nano-Enabled Products

The rapid commercialization of nanotechnology-enabled products has inspired renewed debate on and concern with TSCA's core ability to assess the safety of chemical substances, whether new or existing. Detractors argue that TSCA is a product of its time and is structurally incapable of identifying, quantifying, and managing the potential risks of a technology that did not exist when TSCA was enacted over three decades ago. A threshold question EPA was forced to decide, and did in early 2008, was whether a nanoscale version of a chemical substance included on the TSCA Inventory is considered a new

4. Under ChAMP, EPA will complete screening-level hazard and risk characterizations and initiate action, as needed, on some 6,750 chemicals produced above 25,000 pounds per year.

5. 947 F.2d 1201, 22 ELR 20037 (5th Cir. 1991) (finding fundamental errors in EPA's approach and rationale for banning existing asbestos-containing products).

or existing chemical.[6] Prominent public health interest groups urged EPA to consider nanoscale versions of TSCA Inventory-listed bulk chemicals "new" and thus subject to EPA review and premarket approval under EPA's TSCA §5 new chemicals program. In its final "General Approach" document issued on January 28, 2008, EPA confirmed that a nanoscale substance that has the same molecular identity as a substance listed on the Inventory is considered an existing substance.

EPA's well-reasoned document makes perfect sense within the confines of TSCA. It did not, however, satisfy TSCA detractors and fueled critics' claims that TSCA is irrational. The explosion of nano-enabled products on the market has provided a ready-made and fairly compelling platform for TSCA detractors to point to, in their words, the absurdity of an antiquated law that denies EPA jurisdiction to review as "new" chemical substances engineered precisely for their new physical and chemical properties. While this overly simplistic accusation does not fairly delineate EPA's authority under TSCA, it does confirm that domestic chemical reform will need to address the new versus existing issue. Congress will be under considerable pressure to focus more on actual chemical use patterns and the exposure and risk opportunities they may present, rather than relying upon when a chemical was first introduced into commerce to dictate the government's oversight of it. REACH cannot help but serve as a compelling and ready-made template for TSCA reform measures in this regard.

C. Maturing of Consumer Chemical Awareness

Consumer awareness of and concern with chemical exposures have greatly matured in recent years. The tidal wave of biomonitoring data washing ashore the banks of the Internet from federal, state, public health, and nongovernmental organization (NGO) stakeholders are cited as proof that we live in a rogue chemical nation without meaningful laws, limitations, or respect for personal biological boundaries free from "chemical trespass." This enhanced awareness is evidenced in the proliferation of state, local, and private-sector chemical-specific bans and related measures that populate the legislative and commercial landscape. These initiatives, according to some, are needed to shore up TSCA's inadequacies in managing the risks believed to be posed by chemicals.

Closely related to the availability of these biomonitoring data is the maturation of analytical methods capable of generating them. While occupational safety and health regulatory agencies have used biomonitoring data for decades, their utility outside the workplace as indices of chemical exposure is of relatively recent origin. Vigorous and high-profile NGO campaigns have taken the debate about the perceived harm caused by chemical exposure to a new, deeply personal level, and to great effect.[7] The relevance of these data is less about informing the content of specific statutory reform measures and more about highlighting the need for chemical management reform in general. The "toxic trespass," which some believe evident from biomonitoring data, also confirms, in their view, the need for chemical reform.

D. Retailer Initiatives

Private-sector commercial stewardship initiatives like Walmart's Chemical Intensive Products (CIP) Sustainable Value Network are causing a sea of change in the marketplace. Under these initiatives, EPA and state regulators need to make room for a new sheriff, armed with commercial clout rather than enforcement authority. The CIP employs a chemical screening mechanism intended to diminish and/or prevent the marketing of products that contain chemical substances deemed inconsistent with the retailer's commitment to sustainability because they could potentially adversely affect human health and the environment. The CIP and similar sustainability codes and practices are having, and will continue to have, a profound effect on the design and marketing of consumer products, particularly in the food and beverage, durable goods, and personal care sectors of the economy.

As with biomonitoring data, some contend that private-sector codes of practice, like the CIP, evidence TSCA's failures. Whether this is true remains at issue and is perhaps less important than the perception that it is true. What is clear is that if TSCA reform is to be commercially relevant to the retail community, reform measures will need to address the concerns motivating the development of these sustainability initiatives while at the same time seeking to provide commercial comfort to manufacturers who are increasingly concerned about the apparent erosion of government standards in favor of unpredictable and inconsistent private-sector standards.

II. A Game Plan for Chemical Reform

Most stakeholders would agree that domestic chemical reform is needed. There is little agreement, however, as to how to go about undertaking this process, or even what the product of chemical reform might look like. Domestic stakeholders need to develop a game plan to provide much needed focus on what must be done to achieve a positive result. Here are a few thoughts on developing one that offers the best opportunity for a successful outcome.

A. Understand the Implications of Global Chemical Management Programs

Chemical manufacturing and distribution is a global enterprise, and international chemical management programs such

6. *See* U.S. EPA, TSCA Inventory Status of Nanoscale Substances—General Approach, 73 Fed. Reg. 4861 (Jan. 28, 2008), *available at* http://epa.gov/oppt/nano/nmsp-inventorypaper.pdf. In its guidance, EPA reaffirms its policy not to use particle size to distinguish, for TSCA Inventory purposes, substances that are known to have the same molecular identity. EPA states that molecular identity is "based on such structural and compositional features," including the types and number of atoms in the molecule, the types and number of chemical bonds, the connectivity of the atoms in the molecule, and the spatial arrangement of the atoms within a molecule. Chemical substances that "differ" in any of these structural or compositional features, according to EPA, have different molecular identities.

7. *See*, *e.g.*, Environmental Working Group, *Homepage*, http://www.ewg.org (last visited Nov. 20, 2008).

as REACH and related chemical programs need to be considered, analyzed, and understood before domestic changes are considered in earnest. REACH implementation is underway and chemical manufacturers with a global presence have already preregistered their chemical products under REACH. Their perspective on domestic chemical reform may be different, and perhaps considerably so, than pre-REACH. This is not to suggest that these players believe domestic chemical regulation is unimportant or that TSCA is irrelevant. Rather, it means REACH is a game changer, the stakes of domestic chemical reform are different than before, and REACH's immediate and long-term implications need to be factored into the mix to assess meaningfully the extent and consequences of domestic chemical reform initiatives. In particular, it will be important to understand what works under REACH and what does not, whether perceived failures are because of flaws in REACH or implementation errors, and whether decisions are being made under REACH based on credible science or perceptions of risk whether well founded or not.

The July 2008 International Chemical Secretariat (ChemSec) release of the Substitute It Now (SIN) List is a case in point.[8] The unsubtle SIN list identifies a set of chemicals with the aim of ensuring that "[a]uthorisation is an effective tool to fast-track the most urgent Substances of Very High Concern for substitution, and to facilitate toxic use reduction by business." To a more jaded eye, the ChemSec SIN list is a transparent means to hasten the substitution of chemicals presumed to be in need of replacement without affording their manufacturers and downstream users the carefully defined procedural steps contemplated under the REACH authorization process. Domestic chemical reform can learn from REACH's implementation and use what is good and refine what is not working.

In addition to REACH, the Canadian Environmental Protection Act (CEPA)[9] and Health Canada's innovative Amendments to CEPA should also be reviewed and considered. In Canada, there are approximately 23,000 substances that can be manufactured in or imported into and used commercially in Canada that comprise the Domestic Substance List and that have not been assessed for the risks they may pose to the environment or human health. The Amendments to CEPA provide more processes for assessing these substances to determine if any is CEPA-"toxic." Chemical substances determined to be toxic are subject to restrictions to reduce or eliminate the release of the substance into the environment.

More detail on the REACH and CEPA programs is beyond the scope of this Article. The point is domestic chemical reform cannot and should not occur in a geographical vacuum. The globalization of chemicals in commerce is a reality, and the impact of international chemical management legislation and implementation measures must be identified and considered carefully before undertaking domestic chemical management reform.

B. Understand the Implications of and Interplay Among Domestic Chemical Management Programs

U.S. chemical management does not begin and end with TSCA. Domestic chemical management covers a lot of real estate and includes TSCA, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Food Quality Protection Act (FQPA), the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Hazardous Substance Act (FHSA), the Consumer Product Safety Act (CPSA), the Consumer Product Safety Improvement Act (CPSIA), and the Emergency Planning and Community Right-To-Know Act (EPCRA), among other statutes. Exactly how each of these authorities regulates chemicals must be considered, assessed, and understood before domestic chemical management reform proceeds. Experience has demonstrated that the silo effect of past statutory and regulatory approaches to chemical management has embedded shortcomings that greatly diminish the ability of each statute to control effectively and efficiently the collective impact of chemical releases on human health and the environment.

Another important component of domestic chemical management is the role of state and local chemical management controls. Several state laws have implications far beyond their borders, including California's Proposition 65 and the Massachusetts Toxics Use Reduction Act, among others. Lessons learned from these programs, and the impact of each on the commercialization of chemicals, must be considered, assessed, and understood before federal chemical management reform is undertaken. California's passage in 2008 of a Green Chemistry Initiative (AB 1879 and SB 509) and Governor Arnold Schwarzenegger's signature on September 29, 2008, of the program ushers into law what some regard as a paradigm shift in approaches to chemical management. The Green Chemistry Initiative authorizes, among other things, California's Department of Toxic Substance Control (DTSC) to develop regulations that create a process for identifying and prioritizing chemicals of concern and to develop methods of analyzing alternatives to existing chemical substances. The DTSC is empowered to take a range of actions, including no action and imposing restrictions and/or chemical bans. How this initiative, and other state and local chemical control measures, will impact domestic chemical management must be carefully considered and assessed before federal reform proceeds.

In this regard, the debate would benefit greatly from development of one or more top-flight analyses of these programs, as well as domestic chemical management initiatives, their actual and intended results, their impact on TSCA and other domestic chemical management authorities, a "gap" analysis of the differential between what chemical risk issues are addressed under existing measures and what are not, what can be improved and how, and related topics. The Environmental Law Institute and other independent nonpartisan organizations can provide invaluable assistance in outlining an intellectual construct to guide the debate on these issues.

8. *See* ChemSec, *SIN List*, http://www.chemsec.org/issues/reach/REACH_sin_list.php (last visited Nov. 20, 2008).
9. Canadian Environmental Protection Act, Sept. 14, 1999, C-15.31 (entered into force Mar. 31, 2000).

C. Ensure Key Congressional Staff Are Well Informed

The patchwork of federal statutes, the sometimes conflicting regulatory programs each has spawned, and the role of state, local, and private-sector chemical control measures are challenging topics to master. Busy congressional staff must address dozens of priorities on the best of days, and finding the time to learn about and understand chemical management issues is a tall order. Interested stakeholders must commit to a process that will ensure congressional staff are adequately briefed on these complicated issues. The success of any legislative product that emerges over the next several years will depend, in part, upon the quality of the information base from which congressional staff and members will be working.

D. Work Hard to Identify Common Principles

Chemical reform stakeholders represent a uniquely diverse group of interests with disparate views. Lawmakers, regulators, industry interests, public health, and public interest groups do not always agree on the details of getting to "yes," but may potentially agree on fundamental joint principles upon which a new approach to chemical regulation could be based. A few guiding principles that may help stakeholders to try to reach common ground include:

- *Prioritize*. Stakeholders must focus sharply on the limited resources with truly deserving objectives based on actual potential to pose harm. A related principle is ensuring federal agencies are adequately resourced, reversing a troubling trend of the recent past.
- *Build public trust*. Regardless of the merits of the need for chemical reform, TSCA has an image problem and the public trust is an essential component of effective chemical management. This point has been repeatedly made in the context of stewarding the responsible commercialization of nanotechnology, and certainly applies more broadly to chemical management in general. The public must have faith in the government's ability effectively to oversee chemicals through their life cycle. Even the most brilliant of plans will fail if this important principle is not embraced and joint efforts are not employed to achieve this result.
- *Avoid de facto chemical reform*. Change should occur, if at all, as a result of a thoughtful, deliberative process, and not because state, local, and private-sector initiatives become the *de facto* agents of chemical management reform.
- *Leverage resources effectively*. The discussion above illustrates the need to work closely and often with international agencies to leverage resources efficiently and better than in years past. EPA is already doing a good job of tapping into these resources. The U.S. commitment under the Montebello Agreement,[10] as further refined by EPA's Office of Pollution Prevention and Toxics' ChAMP, illustrates the internationalization of EPA's policy and programmatic efforts. Additionally, EPA's substantial commitment to and leadership in several Organization for Economic Cooperation and Development (OECD) nanotechnology initiatives reflects EPA's interest in leveraging global resources.[11]

While EPA's efforts in this regard are commendable, TSCA legislative reform may be needed to foster international data-sharing. As noted, the protections afforded under TSCA §14 prevent public disclosure of confidential business information (CBI) submitted to EPA, particularly under the PMN program, and these protections are necessary. EPA and others have long maintained that CBI protections can impede the dissemination of important information to international and state regulatory agencies that arguably have a legitimate interest in accessing the information for their own regulatory or other legitimate purposes, even if there are comparable protections for the data under those jurisdictions. Chemical reform may include revisions to TSCA §14 to allow EPA to share CBI with international and state agencies provided that the receiving entities have in place protections for CBI comparable to those found in TSCA §14 to protect against inappropriate or unauthorized disclosures.

III. Conclusion

This Article was not intended to outline what domestic chemical management reform should look like. Stakeholders undoubtedly already have a thought or two along these lines and are focusing now on arguments to persuade others to see things their way. Rather, this Article urges stakeholders to do their homework, ensure that congressional staff and other opinion leaders do their homework before commencing a process to achieve chemical reform, and strive to identify a core set of guiding principles that will focus the debate efficiently and effectively. Depending upon the inputs, the process could yield a product of which all are proud, or a spectacular dud that is far worse than doing nothing would have been.

10. In August 2007, the governments of Canada, Mexico, and the United States announced efforts to ensure the safe manufacture and use of industrial chemicals at the Security and Prosperity Partnership of North America Leaders' Summit in Montebello, Quebec. As part of what has come to be called the Montebello Agreement, the three countries agreed to coordinate efforts to assess thousands of industrial chemicals that are produced or imported in volumes above 25,000 pounds per year.
11. Two OECD groups are particularly relevant in nanotechnology areas. In September 2006, the OECD established the Working Party on Manufactured Nanomaterials, which is chaired by EPA's Jim Willis. In March 2007, the OECD created the Committee for Scientific and Technological Policy, which focuses on applications of nanotechnologies.