American Bar Association
Section of Environment, Energy, and Resources

The Chemical-Regulatory Reform Freight Train–All Aboard!

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39th Annual Conference on Environmental Law
Salt Lake City, UT
March 18-21, 2010

ABSTRACT

The call for chemical regulatory reform in the U.S. has gained momentum due to political circumstances having changed considerably since the Presidential election of 2008; the impact that chemical regulation in Europe is having in the U.S.; actions being taken in state legislatures; and the ground swell fueled by environment-oriented Non-Governmental Organizations (NGOs) feeling emboldened by the winds of change. The Administrator of the U.S. Environmental Protection Agency (EPA) and even the White House are speaking about chemical-regulatory reform. Congress has taken up the cause, and the long-forgotten practice of holding oversight hearings concerning EPA's chemical-regulatory program has been rejuvenated. It appears inevitable that Congress will produce a bill for consideration during 2010 and possible enactment during the current Congress. Grass-roots, consumer concerns about chemicals in house-hold products is likely to encourage NGOs and certain members of Congress. Industry trade associations are getting onboard, lest they be overrun. This paper reports on the latest developments and the positions on TSCA reform being staked out by industry trade associations, environmental groups, the Administration, and even on Capitol Hill.

Introduction

The chemical-regulatory reform "Movement" in the U.S. has picked up a head of steam, fueled in equal parts by: (a) the Democratic Party gaining control of the White House and Congress; (b) the desire by some to emulate the European Union's Registration, Evaluation, Authorization, and Restriction of Chemicals (REACh) program; and (c) several states feeling empowered by enacting green-chemistry laws and other requirements. NGOs are stoking the firebox based on their frustrations with the Bush Administration's preference for "voluntary initiatives" in lieu of regulatory controls. Consumer awareness of the presence of specific chemicals of concern in commercial products has only added momentum. Environmental groups and regulators are actively monitoring tissue and blood samples for the presence of persistent toxins in the bodies of babies and those around us[1] -- and private party class action litigants

[1] http://www.gao.gov/new.items/d10419t.pdf.

seeking to make use of such data cannot be far behind. Reports issued by the Congressional Research Service[2] and the Government Accountability Office[3] have provided further incentives for reform. Observers in Washington comment with confidence that Congress will attempt a complete rewrite of the U.S. chemical-regulatory framework in the near term by overhauling the 33 year-old Toxic Substances Control Act (TSCA). Hearings have already been held in the House and in the Senate during 2009 and 2010 increasing the possibility that a bill will be in play and more hearings in the works during the course of 2010. Even if Congress cannot or does not act legislatively, the Administration appears hell-bent on reinvigorating the Nation's program for addressing the health and environmental risks associated with the thousands of chemicals in commerce.

Background

Before TSCA was enacted in 1976, federal environmental law consisted almost entirely of statutes that provided EPA the authority to regulate risk on a "media-specific" basis (e.g., the Clean Air Act). Other federal laws directed agencies such as the Food and Drug Administration or the Consumer Product Safety Commission to regulate categories of end-use products (e.g., drugs, toys) -- typically without an eye toward mitigating hazards to the environment that might be caused by the production or use of such products. TSCA was considered innovative, because with it, Congress granted EPA authority over the entire life cycle of regulated chemical substances, from chemical manufacturing and processing (including incorporating chemicals into other products and articles), to use and finally disposal. Moreover, EPA was provided authority to take action to call-in existing data concerning chemicals in the market place, to order new tests when data were insufficient for EPA's purposes, and to impose regulations intended to control unreasonable risks to human health or the environment presented by chemical substances in commerce (including on *new* chemicals *before* they might enter commerce).

EPA has had success implementing certain aspects of TSCA, such as the new chemicals ("premanufacture") review program. The Agency also has effectively contained and considerably reduced the risks from certain "legacy" uses of known hazards such as PCBs, lead, and asbestos. However, since its enactment more than 30 years ago, the core provisions of TSCA have never been amended to take into account changes in scientific/technical, economic, and regulatory paradigms. Moreover, EPA's recent reliance on voluntary initiatives, and its failure to act authoritatively to control risks on a significant number of existing chemicals with known hazards, has been a source of continuing criticism among environmental groups and others.

It is against this backdrop that TSCA Reform "freight train" began its forward motion.

Influences for Reform from Within and Abroad

An important development in recent years has been the emergence of state government efforts to exert control over risks related to chemical substances. Several states have undertaken broadly-based programs that go beyond actions on specific chemicals.[4] Successes in state-based

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[2] http://assets.opencrs.com/rpts/RL34118_20080718.pdf.

[3] http://www.gao.gov/new.items/d10292t.pdf.

[4] Washington State's "Children's Safe Products Act"(Washington State, House Bill 2647, 2008; http://www.ecy.wa.gov/programs/swfa/cspa/). California's Green Chemistry Initiative http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/GREEN_Chem.pdf

initiatives have been influenced by and have further encouraged NGO and web-based efforts to legislate for chemical regulatory actions in a number of states beyond the west coast. The proposition that soon there could be a multitude of states each with differing chemical regulatory programs has provided an incentive for the regulated industry to consider the benefits of federal (and perhaps peremptory) legislation updating TSCA. Recently, a coalition of states has issued its own recommendations for reform of the federal chemical regulatory program.[5]

Perhaps equally influential has been the impact of the European Union's regulation known as REACh (for the Registration, Evaluation, and Authorization of Chemicals)[6] on perceptions in the U.S. about the need for regulatory reform here. REACh represented a major shift in the regulatory paradigm for commercial chemicals world-wide by creating a registration program for all chemicals on the market in the EU (both existing chemicals and newly-entering substances). Perhaps the central attribute of REACh that has garnered the greatest favor in the U.S. among activists is the construct that the "burden of proof" has been shifted from the government to industry. Many also find it compelling that REACh avoids unnecessary animal testing by requiring data sharing and enforces risk-communication principals by requiring that information concerning risk be transmitted along the value chain between chemical producers, processors, and users. If the European model has given regulatory reform sex appeal, then the Canadian chemical-regulatory reforms enacted in 1999 to modernize the Canadian Environmental Protection Act (CEPA)[7] have allowed hopefuls in the U.S. to say to themselves, "if wholesale reforms can be accomplished on this continent, then there's hope that the U.S. can update its program too". The key features of REACh (and perhaps CEPA) are going to figure prominently in the debate over chemical regulatory reform legislation in the U.S.

Impact of the Election of 2008

The importance of the election of President Obama to making TSCA reform tangible cannot be overstated. The election's theme of change, and the President's coattails, invigorated Democrats in Congress, environmental NGOs, and even EPA managers and staff who had been frustrated that TSCA has not played a more vital role of the Nation's chemical-regulatory system in recent years. In an effort to lead the charge, then-new EPA Administrator Lisa Jackson was called in September 2009 to announce the Obama Administration's "core principles" for legislative reform of TSCA. The Administration's "Essential Principles for Reform of Chemicals Management Legislation" are intended to give the Agency what it needs to expediently take action to regulate chemicals of concern and promptly assess and regulate new chemicals before they enter commerce.[8] The principles include:

- Chemicals should be reviewed against risk-based safety standards based on sound science and protective of human health and the environment.

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[5] http://www.maine.gov/dep/oc/safechem/13states_sig.pdf.

[6] Regulation (EC) No. 1907/2006. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:en:PDF.

[7] CEPA-1999. Statutes of Canada 1999. Chapter 33.

[8] The "Essential Principles for Reform of Chemicals Management Legislation" can be found at: http://www.epa.gov/oppt/existingchemicals/pubs/principles.html.

- Manufacturers should provide EPA with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or the environment.
- EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account sensitive subpopulations, costs, social benefits, equity, and other relevant considerations.
- Manufacturers and EPA should assess and act on priority chemicals, both existing and new, in a timely manner.
- Green Chemistry should be encouraged and provisions assuring transparency and public access to information should be strengthened.
- EPA should be given a sustained source of funding for implementation.

As if to cover the Administration's bases in the event that chemical-regulatory reform loses momentum and suffers the fate of climate change and health care reform legislation, the Administrator announced a parallel initiative to strengthen EPA's current TSCA/chemical management program and to pick up the pace of the Agency's efforts to address chemicals that present unreasonable risks. Thus, on the same day that she announced the principles for legislative reform, Administrator Jackson also identified an initial list of chemicals for possible risk management actions and reported that EPA would post an initial set of four action plans in December 2009 and will complete and post additional chemical action plans in four-month intervals thereafter.[9] Jackson also pledged to accelerate efforts to gather information from industry that is critical to making chemical risk management determinations. The Agency will use its existing TSCA authorities to fill current gaps in health and safety data on high production volume chemicals; enhance reporting requirements for chemical use and exposure information; and implement requirements for increased reporting on nanoscale chemical materials. In addition, the announcement suggests that EPA is reviewing its prior statements concerning how nanoscale materials are managed under TSCA. True to its word, the Agency already has taken some steps to increase public access to information about chemicals[10] and make public EPA's priorities for future risk management actions.[11]

Non-Governmental Organizations are Riding the Train

The NGOs have truly become the steam in the engine of the reform tank engine. The impetus for change and the goals of the environmentalists movement are being voiced by an increasingly broad array of groups, all of whom seem to have articulated either their generalized support of specific legislation,[12] or to have espoused core principles for reform upon which many of the groups appear to agree. Among the key contributors to the debate has been Richard Dennison, of the Environmental Defense Fund, who has written extensively on this topic of

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[9] Information about EPA's enhanced chemical management program, and the initial list of priority chemicals can be found at: http://www.epa.gov/oppt/existingchemicals/index.html.

[10] http://www.regulations.gov/search/Regs/home.html#documentDetail?R= 0900006480a80fe4.

[11] http://www.epa.gov/oppt/existingchemicals/pubs/ecactionpln.html.

[12] http://www.ewg.org/files/KSCALetterSignatures.pdf; http://www.edf.org/pressrelease.cfm?contentID=7895.

TSCA and the need for reform and who more than a year ago, in the *Environmental Law Reporter*, articulated the following set of reform principles:

1. Establish a policy and develop and apply criteria to identify and act to control all chemicals of concern.
2. Separate scientific decisions as to whether a chemical is of significant concern from policy decisions as to how best to address such concerns.
3. Eliminate the all-or-nothing approach to regulation under TSCA.
4. Shift the burden of proof from government to demonstrate harm to industry to demonstrate safety.
5. Require comprehensive hazard information as a condition for existing chemicals to remain on, and for new chemicals to enter, the market.
6. Require robust data on chemical uses and exposures.
7. Improve integrity and credibility of industry-generated data.
8. Broaden public access to chemical data.
9. Tighten conditions under which industry can claim its submissions as confidential business information.
10. Allow state governments to undertake more protective actions.

http://www.edf.org/documents/9279_Denison_10_Elements_TSCA_Reform.pdf.

The Industry Climbs Aboard

Not to be left out, and sensing the possibility of getting out-flanked by the NGOs who appear to have the ears (and legislative drafting pens) of a few prominent members of Congress and the Senate, various industry and trade organizations began to formulate positions and look for common ground. Thus, the Consumer Specialty Products Association (CSPA)[13] and the Society of Chemical Manufacturers and Affiliates (SOCMA) and other well-known trade associations articulated their principles for chemical regulatory reform.[14] The American Chemistry Council (ACC), the largest and most heavy-hitting of the bunch, put forth these principles (which might be difficult to distinguish if left anonymously to be read side-by-side with the Administration's and EDF's principles):

1. Chemicals should be safe for their intended use.
2. EPA should systematically prioritize chemicals for purposes of safe use determinations.
3. EPA should act expeditiously and efficiently in making safe use determinations.

[13] http://www.cspa.org/infocenter/our-issues/principles-for-chemicals-management-policy/.

[14] http://www.socma.com/assets/File/socma1/PDFfiles/GR_PDF_files/ SOCMAsApproach-to-CRM-in-2009andBeyond.pdf.

4. Companies that manufacture, import, process, distribute, or use chemicals should be required to provide EPA with relevant information to the extent necessary for EPA to make safe use determinations.

5. Potential risks faced by children should be an important factor in safe use determinations.

6. EPA should be empowered to impose a range of controls to ensure that chemicals are safe for their intended use.

7. Companies and EPA should work together to enhance public access to chemical health and safety information.

8. EPA should rely on scientifically valid data and information, regardless of its source, including data and information reflecting modern advances in science and technology.

9. EPA should have the staff, resources, and regulatory tools it needs to ensure the safety of chemicals.

10. A modernized TSCA should encourage technological innovation and a globally competitive industry in the United States.

http://www.americanchemistry.com/s_acc/sec_article_acc.asp?CID=2178&DID=9939.

Congress -- Careful Engineer or Conductor on a Runaway Train?

Not only does Congress appear poised to act in this session, it had shown some life during the last Congress when Senator Lautenberg and Representative Waxman both introduced versions of the Kids Safe Chemicals Act (http://lautenberg.senate.gov/ newsroom/record.cfm?id=298072&).

TSCA-related hearings have started to abound, a phenomenon unheard of during the preceding 15 year period. During 2009, hearings were held in both chambers during which TSCA reform and reauthorization were considered. On November 17, 2009, the House of Representatives' Committee on Energy and Commerce; Subcommittee on Commerce, Trade and Consumer Protection held a hearing to discuss "Prioritizing Chemicals for Safety Determination." Committee members heard testimony concerning methods for prioritizing chemicals for potential review and regulatory action under a reinvigorated TSCA.[15] Following on the heels of the House hearing, the Senate's Committee on Environment and Public Works and the Subcommittee on Superfund, Toxics and Environmental Health held a joint oversight hearing on December 2, 2009 to address TSCA. Two hearings have already been scheduled for the early part of 2010 and more appear to be coming down the track.[16]

It is anticipated that Senator Lautenberg will introduce a new version of the Kids Safe Chemical Act in the Senate, perhaps collaboratively, with Representative Bobby Rush, who

[15] Statements and testimony from the hearing can be found at http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1820:prioritizing-chemicals-for-safety-determination&catid=129:subcommittee-on-commerce-trade-and-consumer-protection&Itemid=70.

[16] http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=8a722315-802a-23ad-4e9a-b8477139e63f

would introduce a version in the House. In spite of the fact that key staff on both the House and Senate sides have been meeting with the trade organizations, many indications are that the new bills will still look like a lot like "Kids Safe One" and will very much be in keeping with preferences of key NGO leaders who seem to continue to hold considerable sway in the backroom drafting process.

Why the Train Might yet Derail

While all the key players seem to aspire to principles that are remarkably common themes, as with all matters related to legislation, the *Devil is in the details*. Here is a list of issues that are very likely going to prove to be sticking points:

1. Regulatory Standard. While it appears every one fully expects that Congress will "raise the regulatory bar", there may be a wide divergence as to how to express any "safety standard" in any final version of legislation that could make it to the floor for a vote. (And who can tell us, what really is the difference between "unreasonable risk" and "reasonable certainty of no harm"?) Moreover, sooner or later, someone is going to have to articulate in legislative language what it means to "shift the burden of proof" to industry (and just when and how that will occur).

2. Information Sharing and Confidentiality. Everyone favors "openness" and transparency", but is industry willing to give up on the ability to make confidentiality claims about the identities of newer chemicals. Can producers stomach the idea that EPA might want to collaborate on risk assessments with the more skeptical state officials in the U.S. (think California, Washington, and Maine), international bodies (UNEP, OECD), and even other nation's regulatory agencies -- including passing along confidential production methods and synthesis techniques with the data?

3. Targeting New Technologies. Will legislators be able to resist the temptation to use TSCA reform to explicitly take a bite at addressing nanotechnology, biofuels, and (if it's not too passé) genetically modified materials? During an economic crisis, Congressional steps that could be perceived as stifling U.S. innovation is not likely to be popular in the private sector.

4. Downstream Users, Distributors and Consumers. While chemical manufacturers were the most prominent consideration in the original TSCA debate, the needs of the entire value chain -- all the way down to retailers -- are now going to be key considerations in the debate.

5. Data, Data, Data. EPA wants it, everyone says data has value for value's sake, but really, what will the players be able to agree upon is an acceptable base line for required studies and how easy it should be for EPA to demand more? And just how will biomonitoring fit into the data equation?

6. How Green is Green? It might be a challenge to craft a provision in a revitalized TSCA that can efficiently and carefully move the market place toward encouraging a move to "green chemistry" and "safer substitutes".

Conclusion

For the first time in a generation, there is agreement on the left and the right, and inside and outside of the Washington, D.C. "Beltway" that it is not only appropriate but necessary to modify and even enhance regulatory control over chemical substances which threaten health and the environment. What remains to be seen is whether any common ground truly exists on how EPA should determine what is truly "harmful", and to what extent the Agency should be authorized to take action to reduce potential harms to "zero" when there are economic and perhaps even strategic benefits to the continued use of such substances. Nevertheless, with other legislative initiatives losing steam, the Obama Administration might have to conclude that TSCA Reform may be the centerpiece of its goals for the current session of Congress. It is worth noting, that environmental legislation tends to do well during periods leading up to off-year elections. TSCA Reform may indeed become the little engine that could.