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Has the Chemical-Regulatory Reform Freight Train Been Derailed?

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ABSTRACT

The chemical regulatory reform "movement" benefitted by momentum gained from the Presidential election of 2008 and regulatory developments within several states and the European Union, Recent legislative actions, the upcoming midterm elections, and the unbridled enthusiasm of Non-Governmental Organizations (NGOs) may have become factors that could derail what had appeared to be an unstoppable freight train in favor of the first significant amendments to the Toxic Substances Control Act (TSCA) since its enactment more than 33 years ago. This paper takes a look at the context for chemical regulatory reform and recent events (including recently-introduced TSCA amendments) and asks: "is it possible that the Administration will be able to steer a moderate course that could get the train back on the tracks and make it possible for the TSCA Reform movement to again become the "little engine that could"?

Introduction

The Presidential election of 2008 provided a significant head of steam generating momentum for the chemical regulatory reform "movement" in the U.S. Environmental groups and even "ordinary citizens" have long clamored for greater government oversight of "chemicals" in the environment and in the products we purchase and use in our daily lives. A credible case that the U.S. chemical regulatory regime was overdue for an overhaul was being made on the basis of progress achieved overseas implementing the European Union's Registration, Evaluation, Authorization, and Restriction of Chemicals (REACh) program. When a number of states enacted "green-chemistry" laws and even chemical-specific requirements, it became hard for the chemical producing and processing sectors of American industry not to see the benefit of a more assertive federal role than had occurred under the Bush Administration. Both the Congressional Research Service[1] and the Government Accountability Office[2] have issued reports in recent years arguing the need for reform. Hearings were held this year and last in both the House and Senate concerning the central statute in the U.S. chemical-regulatory framework, the 33 year-old Toxic Substances Control Act (TSCA). In April of this year, Senator Lautenberg introduced TSCA Reform legislation and Congressman Waxman almost simultaneously circulated a "discussion draft" of a similar bill. Both bills clearly reflect: a) long-held frustrations that the U.S.

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

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

Environmental Protection Agency (EPA) in general, and Republican administrations in particular, failed to act to effectively regulate the chemical industry; and b) the sentiment that TSCA might not provide a sufficient mechanism for doing so. The Administration is not prepared to wait for Congress to act, and has opened the throttle for the U.S. Environmental Protection Agency (EPA) to proceed "full-steam ahead" under the existing law to address its own agenda for regulating 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 and 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 in part because Congress granted EPA authority over the entire life cycle of regulated chemical substances, from chemical manufacturing and processing (including incorporating chemicals into other products), through 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 requiring controls on *new* chemicals *before* they enter commerce).

EPA has had success implementing certain aspects of TSCA, such as Section 5 of TSCA, which contains the cornerstone "pollution prevention" provision of the law and provides for EPA to review new chemicals before their entry into commerce in the U.S. (i.e. the "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.

Nevertheless, EPA has been unable to use successfully its authority under Section 6 of TSCA to issue rules which could withstand a legal challenge when the Agency found that a chemical substance will present an unreasonable risk to human health or the environment.[3] In lieu of undertaking the administratively burdensome process of Section 6 rulemakings, the Agency had come to rely on voluntary initiatives. Thus, EPA's 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.

Since its enactment more than 33 years ago, the core provisions of TSCA have never been amended to take into account changes in scientific/technical, economic, and regulatory paradigms. It was against this backdrop that the TSCA Reform "freight train" began its forward motion.

[3] *Corrosion Proof Fittings v. EPA*. 947 F. 2d 1201 (Oct. 18, 1991, rehearing denied, Nov. 27, 1991).

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.[4] Several states have undertaken broadly-based programs that go beyond actions on specific chemicals.[5] Successes in state 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 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.[6]

Equally influential has been the impact of the European Union's regulation known as REACh (for the Registration, Evaluation, and Authorization of Chemicals)[7] 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" on chemical safety has been shifted from the government to industry. Many also find it compelling that REACh avoids unnecessary animal testing by specifically directing that data be shared among registrants. The regulation also 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)[8] 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".

Impact of the Election of 2008

The importance of the election of President Obama to making TSCA Reform tangible cannot be overstated, and he may need to play a moderating role in the legislative process if new legislation is to be realized. 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 played the central role in September 2009 by announcing the Administration's "core principles" for legislative reform of TSCA. The Administration's "Essential Principles for

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[4] http://www.ecos.org/files/3959_file_January_2010_ECOS_Green_Report.pdf?PHPSESSID=5788d30b960c6feb796ffc7f3620d11d.

[5] 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

[6] http://www.maine.gov/dep/oc/safechem/principles.htm.

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

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

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.[9] The principles include:

- Chemicals should be reviewed against risk-based safety standards based on sound science and protective of human health and the environment.
- 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 same fate as climate change 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.[10] 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 action plans in December 2009 and will complete and post additional chemical action plans in quarterly intervals thereafter.[11] Jackson also pledged to accelerate efforts to gather information from industry that is critical to making chemical risk management determinations. The Agency intends to 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 and it is widely expected that "new use" reporting will be required for all nanoscale materials soon.

True to its word, the Agency also has taken some steps to increase "transparency" in government by enhancing public access to information about chemicals, including disclosing the

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

[10] 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.

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

identities of chemical substances which have been claimed to be confidential when included within health and safety data submitted to EPA pursuant to TSCA.[12]

Non-Governmental Organizations are Riding the Train

NGOs have 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,[13] 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 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)[14] and the

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[12] http://www.regulations.gov/search/Regs/home.html#documentDetail?R= 0900006480a80fe4. http://www.epa.gov/oppt/tsca8e/pubs/confidentialbusinessinformation.html.

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

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

Society of Chemical Manufacturers and Affiliates (SOCMA) and other well-known trade associations articulated their principles for chemical regulatory reform.[15] The American Chemistry Council (ACC), the largest and most heavy-hitting of the bunch, put forth these principles (which might be difficult to distinguish from the Administration's and the NGOs' principles if each were placed anonymously side-by-side on the same table):

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.
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?

During the nearly two year period following the presidential election, and the year since the Administration published its own "principles" for TSCA Reform, it has failed to take advantage of the ample number of votes in the Democratic-controlled Congress to introduce its own version of what could have been enacted: a centrist TSCA-Reform bill. Instead, TSCA Reform hearings abounded on the Hill during 2009 and 2010, a phenomenon unheard of during the preceding 15 year period. Thus, within the past 12 months, hearings were held in both chambers during which TSCA Reform and reauthorization were encouraged by virtually every witness. 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

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

concerning methods for prioritizing chemicals for potential review and regulatory action under a reinvigorated TSCA.[16] 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. Additional hearings were held in the Senate in February 2010 and during March 2010 in the House, and more hearings appear to be coming down the track.[17] During each, the members were regaled with complaints about the overwhelming failings of the Agency under previous administrations for their inability to take action to regulate risks.

At long-last, in April, Senator Lautenberg introduced The Safe Chemicals Act of 2010.[18] The bill would amend TSCA in ways too numerous to review in this paper. However, the "highlights" of the bill include:

1. A requirement that manufacturers develop and submit a "minimum data set" for each chemical they produce, while giving EPA authority to request additional information by issuing immediately-effective administrative orders, without having to undertake notice-and-comment rulemaking.

2. Significant expansion of the new chemical notification program to require reporting to EPA before any new manufacturer or processor enters the market or any *new uses* are commenced by any entity that manufactures or processes an existing chemical.

3. Amendments imposing a new "safety standard" on all chemicals (both new and existing substances) and regulatory review processes intended to place the burden of proving that a substance meets that standard on the shoulders of manufacturers and processors of the substance. Thus, a proponent of substance would need to demonstrate that any proposed new substance, and any new use of an existing chemical it wishes to commence, will conform to a safety standard that will provide a "reasonable certainty of no harm" -- taking into account both aggregate and cumulative exposures to the chemical from all uses and considering potential effects on any vulnerable sub-population (e.g., kids, the elderly, workers).

4. Provisions under which EPA will categorize and prioritize chemicals for regulatory actions based on risk, and focus resources on evaluating those most likely to cause harm.

5. Significant changes to the way in which EPA manages information and protects trade secrets. Not only will it be more difficult for entities submitting information to EPA to claim it to be confidential, under the proposed legislation EPA will be required to provide public access to health safety and certain chemical use information the Agency obtains on regulated chemicals,

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[16] 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.

[17] http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=8a722315-802a-23ad-4e9a-b8477139e63f.
http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1915:tsca-and-persistent-bioaccumulative-and-toxic-chemicals-examining-domestic-and-international-actions&catid=129:subcommittee-on-commerce-trade-and-consumer-protection&Itemid=7.

[18] http://lautenberg.senate.gov/newsroom/record.cfm?id=323863&.

and to establish a public database for the information submitted by chemical manufacturers and the technical analyses contained in the Agency's own safety determinations.

6. New programs to promote the development of "green chemistry" by providing for grants and research centers to encourage "safer" alternatives to existing chemicals.

On the House side, there is a "discussion draft" of a very similar bill which has been circulated, and there has been a series of discussion sessions among "stakeholders" during which legislative staff, NGOs, the producers and processors of chemicals, EPA managers, and others have participated. A review of the House bill indicates that it "ups the ante" on Senator Lautenberg's version, a further indication that NGO leaders continue to hold considerable sway in the backroom drafting process.

Without dissecting these two pieces of legislation line by line, it is fair to say that both bills are intended not only to completely overhaul TSCA, but to essentially replace it with a profoundly more aggressive approach to the regulation of chemicals and products that contain chemicals. Even ardent proponents of the bill would have to agree that the TSCA Reform legislation under consideration would confer enormous new authority upon EPA and new obligations upon the regulated entities -- including perhaps for the first time, placing significant reporting and regulatory burdens upon the commercial entities that merely formulate chemicals into end-use products for sale and distribution at the consumer retail level.

If the bills under consideration today are enacted, everyone can finally say America's TSCA "grasp" far exceeds Europe's "REACh."

Has the Train Already Derailed?

Before the Lautenberg bill was introduced, and the House discussion draft placed into circulation, it appeared the key players all were aspiring to legislate along the same basic principles. However, the terms of the bills under consideration suggest that no one is at the controls and the TSCA Reform Freight Train may have jumped the tracks. Here is a significantly abbreviated list of issues about which there is very little agreement:

1. Regulatory Standard. While it appears every one fully expected that Congress should "raise the regulatory bar", there is a wide divergence as to how to express the "safety standard" in any final version of legislation that would be likely to make it to the floor for a vote. Is it possible a respected and "neutral" moderate member of the House or Senate can help to identify words that fall somewhere agreeably between "unreasonable risk" and "reasonable certainty of no harm"?

2. Information Sharing and Confidentiality. Everyone favors "openness" and "transparency", but it is for very good reason that industry is unwilling to give up on the ability to make confidentiality claims about the identities of newer chemicals. Even if chemical producers can get comfortable with the idea that EPA might want to share confidential information with other governmental bodies in order to collaborate on risk assessments, they are not likely to be able to get behind legislation that would compel EPA to release to the general public (and hence industrial competitors both at home and abroad) the specific identities of chemical substances that are under development and just gaining traction in the market.

3. Targeting New Technologies. Terms in the new bills seem intended to position EPA to be able to use TSCA to take a crack at aggressively regulating 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 are not likely to be popular in the private sector -- and will be perceived as yet another incentive to move R&D and manufacturing operations safely overseas and out of EPA's reach.

4. Registration Versus Reporting. Chemical manufacturers and their customers who purchase and process their products are not inclined to have to register with EPA every existing use of a chemical nor seek EPA's permission to commence any new use they discover for an existing chemical. Yet, this is precisely what both bills would require.

5. Downstream Users, Formulators and Distributors. The bills' minimum data set requirements and "new use" reporting provisions will most assuredly bring many more industries under the Agency's microscope (and into the "public eye"). These provisions open an entirely new front in the apparent "war on chemicals" and likewise, the legislation will now have a far larger number of newly-invigorated detractors capable of undermining any hope for passage.

5. Data, Data, Data. EPA wants it, and everyone says data have value for value's sake, but really, will the players be able to agree upon an acceptable minimum data set and be willing to accept how easy both bills make it for EPA to simply demand more without some administrative process?

6. How Easy Can We Make it for EPA? Throughout both bills, EPA is granted broad and sweeping authority to regulate chemicals and uses -- and with little or no procedural safeguards provided to the regulated community to comment on regulations, nor to challenge EPA actions in court. The bills' authors have given ample incentives for chemical producers and processors to look for ways to simply scuttle in reform movement generally, and by pointing at these bills in particular.

Conclusion

For the first time in a generation, there has been a palpable level of 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. However, the proposed legislation has "pushed the pedal to the floor" and proponents of Reform on both sides may soon find that they no longer have even a fundamental, mutual understanding about the wisdom of opening TSCA up for repairs. In fact, it has been rumored that the regulated community has stopped looking for common ground with the NGOs in favor of finding a friendly Republican member to play the role of a "Snidely Whiplash" who can discretely remove a few ties beneath the rails and sneer wickedly as the Reform Movement Express not only leaves the tracks but plunges headlong off "the Hill." With so many other legislative initiatives losing steam, and in search of an achievable legislative victory, it might be best for the Administration if the President became a voice of moderation and stepped in to advise certain members on the need to come up with a new bill that can get the train back on tracks, around the bend, and steer it safely back down the straightway

before the votes are no longer there to accomplish their goals in the current Congress. If the Administration can still pull that off, as an off-year election still looms in the months ahead, then it can surely be said that TSCA Reform was the little engine that could.