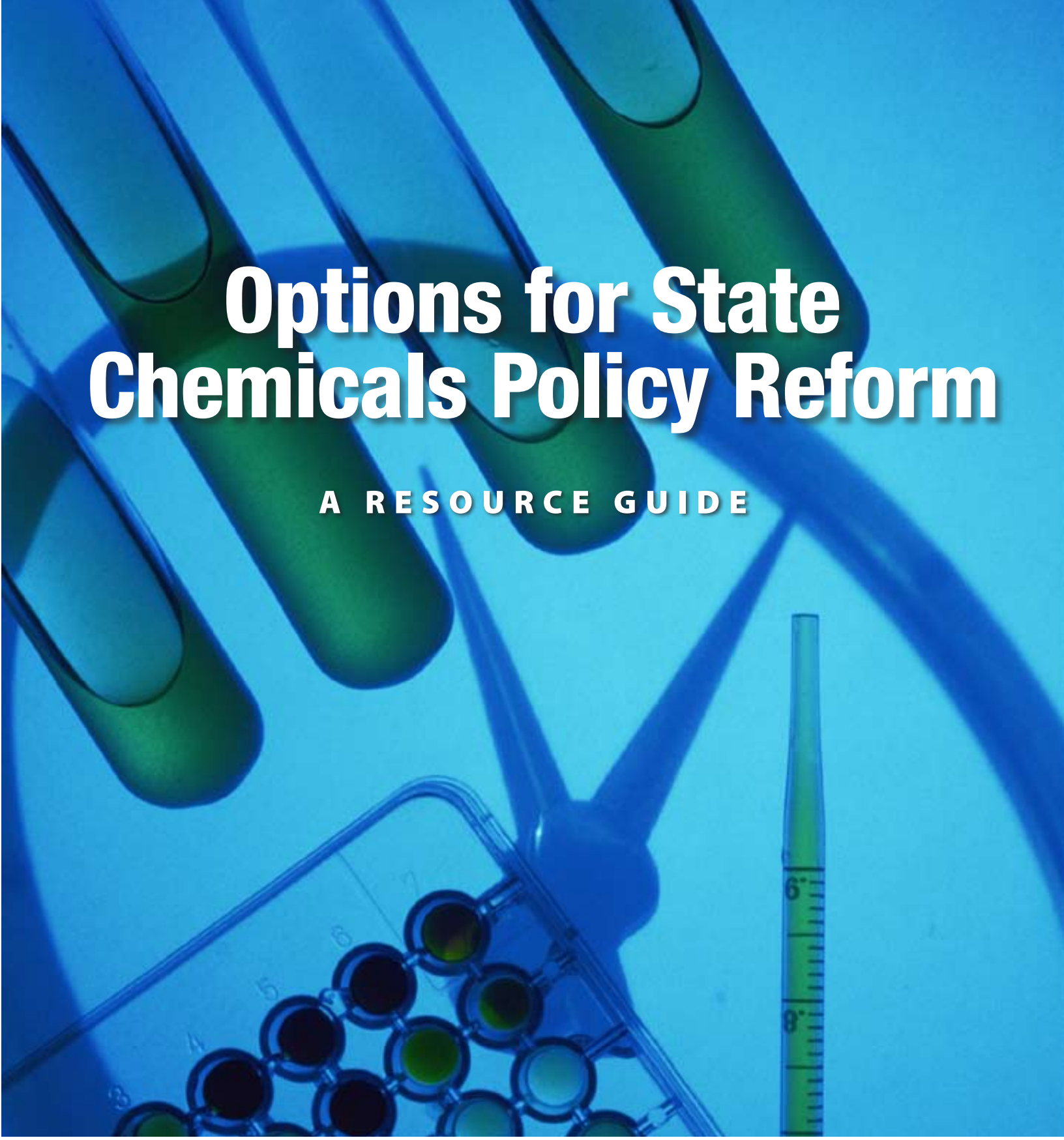

Options for State Chemicals Policy Reform

A RESOURCE GUIDE

Lowell Center for Sustainable Production
University of Massachusetts Lowell

January 2008

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The Lowell Center for Sustainable Production

The Lowell Center for Sustainable Production (LCSP) uses rigorous science, collaborative research, and innovative strategies to promote communities, workplaces, and products that are healthy, humane, and respectful of natural systems. The Center is composed of faculty, staff, and graduate students at the University of Massachusetts Lowell who work collaboratively with citizen groups, workers, businesses, institutions, and government agencies to build healthy work environments, thriving communities, and viable businesses that support a more sustainable world.

This report was produced by LCSP's Chemicals Policy Initiative, whose objectives are to significantly advance policy dialogue on reforming chemicals policy in the United States; assist in the development of sustainable chemicals management outside the US; encourage the development and use of safer alternatives by creating and promoting a comprehensive framework for alternatives assessment; and identify tools and appropriate ways of assisting green chemistry innovation and safer supply chain management of chemicals.

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A RESOURCE GUIDE

EXECUTIVE SUMMARY

January 2008

LOWELL CENTER FOR SUSTAINABLE PRODUCTION
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The full report is available at
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EXECUTIVE SUMMARY

Options for State Chemicals Policy Reform: A Resource Guide

The primary law in the United States that regulates industrial manufacture and use of chemicals, called the Toxic Substances Control Act (TSCA), is now 30 years old and has proved largely ineffective in restricting problem chemicals in commerce or in minimizing or mitigating their harm to humans and the environment. It has also failed to effectively stimulate the development and marketing of safer chemicals and products. Basic toxicity information that is publicly available exists for only a small percentage of the thousands of chemicals in commerce.

The chemical hazards of everyday consumer products are receiving more attention from scientists and others. Our bodies and ecosystems are showing build-ups of chemicals, and research links some chemicals to serious diseases. The public has expressed its concern about tainted foods, leaded toys, and the risks of emerging technologies. State governments have noted the failures of leadership and will at the federal level, the growing public concerns, and the sweeping chemicals overhaul by the European Union (EU), called the Registration, Evaluation and Authorization of Chemicals (REACH) regulation. Many favor change to policies that get hazardous substances out of our homes and communities.

REFORMING STATE-LEVEL CHEMICALS MANAGEMENT POLICIES IN THE UNITED STATES: STATUS, OPPORTUNITIES, AND CHALLENGES

Recent discussions and actions in at least eight states have raised the prospects for change by state and regional governments. Some aspects of chemicals policy can be conducted effectively by states and thereby help catalyze federal action. This report explores **what states can do and how to do it**. A resource guide for state leaders and concerned citizens, this report examines the policy options and structures they might put in place and the critical issues in doing so. With dozens of examples, it also seeks the lessons learned in one place that might be applied elsewhere: what works in Massachusetts may work in Oregon.

If there are multiple reasons to act now, such as those mentioned above, there also are many **challenges to reform** of chemicals policy, among them:

- Limited agency resources and capacity;
- End-of-life considerations in product lifecycles;
- The market entrenchment of many dangerous chemicals and products;

- Jurisdictional issues; and
- Dealing with market imports.

Chemicals management is a complex endeavor and regulation of hazardous chemicals is a scientific and policy activity that requires extensive technical expertise, funding, and data controls. The need to make good judgments in the face of scientific uncertainty can be difficult for government agencies as is the fact that decisions must be made at the nexus of public and private interests. Regulated entities often fight constraints on their ability to market and sell their products.

A report in California has identified three **failures of current policy**:

- **The Data Gap:** Little information is known about the health effects, exposures, and uses through supply chains and the general economy of a large percentage of chemicals in the marketplace. Gathering sufficient data and characterizing it so the public and businesses can use it is critically important.
- **The Safety Gap:** The U.S. has a disjointed and disorganized infrastructure to manage chemicals. Limited authorities curb what is possible. Burdens of proof are heavy — agencies must demonstrate each chemical's risks before they can act preventively. Under TSCA, chemicals in use in 1980 were assumed to be safe until experience demonstrated that they posed an "unreasonable risk." Further, science has learned more about the hazards of chemicals widely used in consumer products. Research has revealed that even small exposures to some substances at certain periods of development can cause serious health effects.
- **The Technology Gap:** The current system provides few incentives to encourage use of safer chemicals. Governments must produce regulatory and market drivers to catalyze the development of safer chemicals.

Some government policies, particularly those adopted internationally, have targeted certain chemical classes as priorities for action:

- Ozone-depleting substances;
- Chemicals that are persistent, bioaccumulative, and toxic to humans or aquatic organisms;
- Very persistent and very bioaccumulative; or
- Toxic to humans, for example,
  - Carcinogenic;
  - Mutagenic (or genotoxic); or
  - A reproductive or development toxicant.

But new scientific knowledge now makes clear that we must do better to identify chemicals that fall into these categories and to address additional hazard categories.

Different laws govern different classes of chemicals. This report relates to **industrial chemicals** used in manufacturing processes and in products, but excludes pesticides or pharmaceuticals,

which are regulated under very different regimens. Re-thinking how we group chemicals in categories to address their inherent hazards is worthwhile but beyond the scope of this report.

A broad and deep reorganization at national and state levels is needed in the policy infrastructure and the decision-making apparatus that control chemicals. Given the tens of thousands of chemicals produced and used in the U.S., data generation, prioritization, and supporting the application of safer chemicals and products is a large task and a significant challenge for governments. It also is tremendously important. This report makes some overarching findings:

- **Manufacturers and users should generate and share hazard, use, and exposure data** needed by consumers, chemical users, and government's policy makers.
- **Processes and policies to ensure the rapid screening, prioritization, and decision-making** on a broad range of chemicals are critical to avoiding chemical-by-chemical assessment and decision-making paralysis.
- **New chemicals policies should encourage the assessment and application of safer, feasible alternatives** to problematic chemicals, and governments should provide tools to companies to undertake such analyses.
- **New chemicals policies must create incentives to innovation and economic development in safer chemicals and products** as well as provide for health and ecological protection.
- **Green chemistry deserves research and financial support** as well as technical and capacity building support for its application in practice**.**
- **State-based and regional initiatives** to control chemicals should be encouraged as pilot and demonstration projects for subsequent larger changes.
- **Chemical reform options can be usefully applied to emerging technologies** as well.

New systems to manage chemicals must incorporate critical elements to: generate chemical information and make it accessible and shared through supply chains; establish processes to rapidly assess, characterize, and make decisions about chemicals; adopt processes to substitute safer alternatives in place of dangerous chemicals; and move to greener chemistry and safer product design through research, innovation, and capacity-building. Rather than reducing risks of chemical exposure to "acceptable" levels, these systems should reduce the inherent toxicity and hazards of the chemicals used in production processes and products.

The report examines the problems, policy options, and examples of these control activities:

- Various approaches to generating information;
- Sharing data through supply chains;
- Screening, characterization, setting priorities, and making decisions;
- Substitution and alternatives assessment;
- Innovation and green chemistry; and
- Policy implementation.

A final chapter looks at how the examined options for chemicals reform might be usefully applied to manage the risks of emerging technologies.

POLICY OPTIONS FOR GENERATING INFORMATION FOR SOUND CHEMICALS MANAGEMENT

Data gaps and limited authorities have plagued the management of industrial chemicals. When a new chemical heads to development, production, and the market, the EPA typically has only a 90-day chance to review it, and it rarely has any actual test data on which to base its review. Unlike virtually all other developed countries, TSCA does not require (or allow EPA to require) new chemical producers to provide even a minimum base set of data on a chemical's environmental fate and behavior, toxicity or ecotoxicity. Although EPA encourages such data to be submitted, they rarely are. Nor do such data typically become available after a chemical enters commerce, even if it is made and used in large amounts. In 1998, the agency found that there was **no** publicly available screening-level hazard data for 43 percent of approximately 3,000 high-volume (at least a million pounds a year) chemicals. Because it must meet substantial evidentiary and procedural burdens to require testing, the EPA has done so for fewer than 200 chemicals since the passage of TSCA. Instead it has turned to voluntary efforts like the U.S. High Production Volume (HPV) Chemical Challenge Program. Launched in 1998 but not yet completed, the program is now providing basic screening-level hazard data for most HPV chemicals.

Good data is the currency of the realm in chemicals policy, Denison observes (see Module 1, Denison). No realistic assessment of a chemical's hazards can be made without adequate data about its effects on health and the environment. Without complete, reliable, and timely data, priorities will be skewed and scientists' efforts to substitute safer chemicals for dangerous ones will be a haphazard exercise. What kinds of data?

- Hazard traits related to health;
- Other hazard characteristics;
- Potential and actual releases;
- Exposures;
- Uses;
- Supply chain flows; and
- Lifecycle management.

Data development (which is more developed for hazard data than exposure data) can occur through: (1) measurement and testing; or (2) modeling or interpolation and extrapolation from available data. In either case, the objective is to identify not only the dangerous chemicals but also the safe or safer ones so they can be used as substitutes for hazardous chemicals.

In the production of data, state governments may choose from several courses of action when it comes to facilitating the reporting or generation of chemical information, each with distinguishing advantages and disadvantages: It can:

- Collect or generate the information itself. This can be done by directly conducting testing of chemicals; by measuring or monitoring for them in workplaces, environmental media, humans or other organisms; or by applying models to develop estimates or predictions in the absence of data. An example of government-developed chemical information is bio-

monitoring of human blood and urine conducted by the U.S. Centers for Disease Control.

- Require commercial producers or users of chemicals to report existing or generate new information. Testing requirements are most commonly imposed at the time of a chemical's first introduction. An example of this approach is the reporting, testing, assessment, and risk management requirements under the Registration provisions of the European Union's REACH Regulation.
- Request that information be provided voluntarily or provide incentives for companies to do so. A prominent example of this approach is the U.S. EPA's High Production Volume Chemicals Challenge Program.
- Help to develop and shape a market in which the collection or generation of the information has economic value. An example is California's Proposition 65 which requires companies that make products containing any chemical "known to the state of California" to be a carcinogen or reproductive toxicant to label the product accordingly. This economically rewards companies that generate information about a chemical that allows a no-effect level to be set, because they can avoid negative labeling.

SHARING KNOWLEDGE ABOUT CHEMICALS: POLICY OPTIONS FOR FACILITATING INFORMATION FLOW

It is not sufficient to gather information about chemicals. Once data exists, that information must flow through the economy to all actors who make decisions about chemicals. Massey (see Module 2, Massey), takes up the issue of information flow among all of the actors concerned. Those actors include chemical manufacturers or suppliers; downstream users of chemicals; purchasers, retailers, and professional users of products containing chemicals; and individual users of consumer products. They also include policy makers, workers, and members of the public.

There are currently large gaps in information flow up and down the supply chain and even among firms making the same products. Actors across the supply chain suffer from communication deficits. State governments can facilitate information flow by requiring disclosure, facilitating communication, and managing data effectively. Opportunities for action at the state level include the following:

- Encourage or require firms to submit information on chemical hazards and on chemical uses. For example, under REACH, firms must submit information on both chemical hazards and chemical uses throughout supply chains to users and government authorities. Much of this information is also made available to the public.
- Encourage or require firms to disclose chemical ingredients of products via labeling or registry requirements. For example, in Sweden, firms must provide information to the Swedish Products Register if they manufacture or import more than 1 ton of eligible products.
- Create incentives for manufacturers to obtain information from suppliers about chemicals in products. For example, the Restriction on Hazardous Substance (RoHS) has created an

incentive for manufacturers of electrical and electronic equipment to improve communication about chemicals up and down the supply chain by prohibiting the sale of electrical or electronic equipment containing certain toxic chemicals.

- Require warnings or labels identifying both acute and chronic health hazards in products or work places. For example, California's Proposition 65 requires that a warning be provided whenever a workplace or product could expose people to chemicals included on an official list of carcinogens and reproductive toxicants. In another example, Pennsylvania has adopted requirements for Material Safety Data Sheets for public-sector work sites that are more extensive than the corresponding federal requirements.
- Facilitate voluntary information sharing within supply chains. For example, the Massachusetts Toxics Use Reduction Institute has convened consortia of firms in the electronics supply chain, creating an opportunity for firms to collaborate with one another to reduce toxics.
- Develop infrastructure for managing chemical information; require that firms submitting information to other government authorities also provide information to the state; and adopt best practices for management of confidential business information (CBI). For example, states may be able to take advantage of the chemical information submitted to European government authorities under REACH. Elements of best practices include ensuring that health and safety information are not eligible for CBI protection; requiring firms to provide justification for CBI requests; placing a time limit on CBI claims granted; sharing CBI-protected information with governments and affected workers; and other provisions.

ASSESSMENT AND PRIORITIZATION OF CHEMICALS: POLICY OPTIONS FOR STATES AND THE FEDERAL GOVERNMENT

How can governments do a better job screening, prioritizing, and acting on more chemicals, Tickner (see Module 3, Tickner) asks, so they can act preventively and rapidly and do so with consistency and transparency? Some tools exist, but more are needed. In decision-making, it will be important to keep certain questions in mind:

- Are the data sufficient to discriminate between chemicals of great concern and those of low concern?
- Where are the uncertainties and gaps in data and must they be addressed before proceeding?
- Should risk management techniques be applied and do prevention opportunities exist that would circumvent the need for additional study?

Few definite protocols exist for chemicals assessment and prioritization processes which typically are iterative rather than linear. The steps in each process, including decisions made, also may be done in any chronological order and may depend on whether the decision at issue is regulatory or voluntary.

Screening is the dynamic process that constitutes the first evaluation of the hazard data — performed early in the decision-making process — and should focus on avoiding false negatives (that is, finding low or no hazard when, in fact, a hazard exists). While screening data may be incomplete, the advantage of using it in its early form is that the review process is comparatively rapid and may still produce meaningful, though limited, results.

As a precautionary measure in the screening process, the lack of data should be interpreted as evidence of potential concern and should not stall decision-making. The screening process can support decisions to use or not use the subject chemical and it can identify negative attributes, but it **cannot pronounce that a substance is safe.** Other characteristics of screening include:

- Screening may examine only the inherent toxicity of a substance or it also may consider uses and exposures.
- Policy instruments should elevate the search for safe substitutes to the level of the search for chemical hazards since they are needed when substitution becomes the policy choice.
- If a state does not have the resources for adequate screening, it could join with nearby states to collaborate and "regionalize" its efforts. States also might require that industry undertake screening and submit data and/or provide industry with the tools and support to voluntarily screen chemicals.

States have several options for chemical screening, including:

- Providing industry with the tools to undertake regulatory or voluntary screening with agency review. An example of this approach is the U.S. EPA's Sustainable Futures Program which provides extensive tools to industry to screen new chemicals and understand safer designs and synthesis pathways.
- Requiring industry to submit information/undertake screening. An example of this option is the Registration dossier requirement under REACH.
- Undertaking screening on the basis of existing data. The 2000 Danish EPA Classification of dangerous substances provides an example whereby the government screened and classified some 55,000 chemicals on the basis of modeling data.

Assessment, characterization and prioritization are the ways that governments with limited budgets can target their resources most effectively. The efforts should usually include a **categorization process** which sorts and ranks chemicals by applying criteria or methodologies that determine levels of concern. Chemicals may be categorized on the basis of inherent hazard or, also on their exposure potential, use, or production volume. Rapid risk assessments can be useful in prioritizing chemical hazards but decision-making cannot, and should not, be contingent on chemical-by-chemical risk assessments. **Decisions do not require perfect information**; indeed, too often, that demand has thwarted preventive or protective action. Processes are needed to facilitate decision-making on chemicals of elevated concern.

State government options to ensure rapid prioritization and decision-making on chemicals, include:

- Undertaking a government-sponsored rapid classification/prioritization process. An example of this approach is the Canadian Domestic Substances List Classification, whereby 23,000 chemicals in use in Canada were screened with 4,300 chemicals being identified as needing further assessment/action and about 500 chemicals being listed as high priorities for further assessment/action.
- Providing tools to industry to voluntarily undertake substance assessments and prioritization processes as well as challenges to reduce chemicals of concern. Under this option, government agencies would provide tools to industry (such as the SC Johnson developed Greenlist process) and challenge companies to self-classify chemicals, develop lists of chemicals of concern, and develop action plans for reduction of such chemicals.
- Issuing lists of chemicals of high concern, lower concern, and further study, and developing voluntary or regulatory programs/activities to develop data and move firms away from those chemicals. Governments can engage companies in finding and implementing alternatives to high concern chemicals on a voluntary basis, through action plans, technical assistance, procurement programs, demonstration projects, and supply chain dialogs. An example of this option is the Swedish PRIO database and programs undertaken by the Swedish National Chemicals Inspectorate.
- Initiating "authorization" requirements for chemicals identified as higher concern. A model of this approach is the European Union REACH regulation's authorization process.

At the decision-making stage, multiple considerations arise. Briefly, they include:

- What are the legal framework and requirements for action;
- Should decisions be hazard- or risk-based;
- How much data are needed before risk management actions can occur;
- Who (government or industry) should decide;
- What emphasis should be given to risk trade-offs, feasibility, and socioeconomic impact;
- What action, if any, should be taken on the chemicals of lower concern; and
- Where do mandatory versus voluntary actions fit the case?

POLICY OPTIONS FOR CHEMICAL SUBSTITUTION AND ALTERNATIVES ASSESSMENT: DEFINING ENVIRONMENTALLY PREFERABLE SOLUTIONS

Substitution is one policy option whose importance has risen as states have adopted toxics use reduction approaches to risky chemicals in production processes and products, according to Rossi (see Module 4, Rossi). It encompasses changes in materials, products, production processes, design, as well as chemicals. When substitution is employed, it may result in use of a different chemical or a different material or process that could eliminate completely the need for using the risky chemical. For businesses that use or purchase products containing toxics, the substitution tactic involves the following steps, called **alternatives assessment**: 1) identify all

chemicals used in making the product, including its material chemistry; 2) evaluate the hazards of those chemicals; 3) classify them with regard to level of concern; 4) identify alternatives to the chemicals of high concern; 5) work with suppliers to provide safer alternatives; 6) evaluate, compare, and prioritize the alternatives; and 7) select preferred alternatives, that is, substitute lower hazard chemicals for those of higher hazard.

Success in substitution will require a package of policy initiatives that provide chemical use, hazard, and prioritization information; create incentives for safer alternatives and disincentives for using/producing chemicals of high concern; and require action. The following options are available for state governments to support alternatives assessment and substitution, including:

- Government undertaking or sponsoring alternatives assessments. Under this option public institutions would perform alternatives assessments of chemicals to inform policy makers and businesses on the availability of safer alternatives. These can be resource intensive but contain detailed data on the availability of alternatives. An example of this option is the alternatives assessments that have been conducted by the Massachusetts Toxics Use Reduction Institute on high concern chemicals.
- Governments providing technical assistance to firms in implementing safer alternatives. Since "drop in" chemical substitutes often do not exist, technical assistance programs can be effective tools for transferring information about chemical hazard, analytical tools and alternatives availability and implementation. A successful example of government sponsored technical assistance for substitution is the Surface Solutions Laboratory of the Massachusetts Toxics Use Reduction Institute which tests alternative non-chlorinated degreasers for firms to reduce or eliminate the technological and toxicological risks in switching to alternatives.
- Governments requiring firms to undertake substitution and/or toxics use reduction plans. Substitution plans completed by businesses avoid the resource constraints of government-completed alternatives assessments. They require that firms examine feasible alternatives to substitute a chemical of concern. An example of substitution planning is the requirement under REACH that firms applying for an authorization must "analyze the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.
- Governments initiating mandatory restrictions or substitution requirements. Chemical restrictions can range from direct bans to substitution requirements pending availability of feasible alternatives. There are a range of options for restrictions, which often spur innovation in new materials — chemical or use specific, classes of chemicals, etc. An example of chemical restrictions is the restrictions on certain chemicals in electronic and electrical products under the European Commission's Restrictions on Hazardous Substances (RoHS) Directive.

In addition to restrictions, certain options can help spur innovation in safer chemistry, including supply chain options: incentives, information, and technologies that support the generation of environmentally preferable chemicals, in the form of research and development support, green

chemistry centers; tax credits; taxes and fees; and selection policies, which involve government either purchasing or promoting the purchase of environmentally preferable products.

POLICY OPTIONS FOR CHEMICAL INNOVATION AND GREEN CHEMISTRY

Public demand, greater regulation, and government scrutiny are pressuring the chemical industry to seek safer substances and it is developing green chemistry as a result. Green Chemistry is a new way to think about chemical design, employing a set of principles that cut or curb hazardous substances from the production, use, and disposal of chemical products. While Green Chemistry is receiving significant attention in the business and academic communities, efforts to encourage its adoption in practice are slow, piecemeal, and encounter resistance, according to Geiser and McPherson (see Module 5, Geiser and McPherson).

The industry's new-product cycle is 10-20 years long and technology improvements in the sector favor primarily incremental change. Yet, **regulations can drive chemical research** and innovation can produce cost savings. Innovation in chemicals production traditionally means adoption of a chemical or chemical process as part of a commercial application. At first adoption, it is called **innovation**; multiple adoptions are called **diffusion**. A variety of factors affect adoption of new technologies, including:

- **Relative Advantage** — improvement of an innovation over current practices;
- **Comparability** — consistency with existing needs;
- **Complexity** — assessing the difficulty of understanding or using an innovation;
- **Trialability** — degree to which a change can be tried before full adoption; and
- **Observability** — how observable the advantages of change are to others.

State governments have a part to play in support, innovation, and adoption of products of green chemistry. The policy tools they have available include:

- Research and development support into new material and chemical streams. An example is a consortium of state research universities supporting green chemistry such as the New England Green Chemistry Consortium, a collaboration among the public sector universities in New England.
- Technical assistance. The state pollution prevention programs established during the 1990s proved the effectiveness of providing government technical assistance programs to assist firms in meeting environmental objectives. Those states, for example, could integrate green chemistry and chemicals innovation assistance into their ongoing technical assistance programs.
- Education and training. Currently, there is a significant shortage of college students interested in chemistry. Promoting college courses in green chemistry and bio-based materials is an example of encouraging environmentally friendly chemical innovations through education, potentially attracting more students to the field.
- Market interventions. In some markets, government purchasing is so significant that it drives market behavior. Expanding government environmentally preferred procurement

programs to focus on green chemistry promotion is an example of market intervention.
- Economic policies. State governments, for example, could create tax incentives for manufacturing or purchasing greener products, thereby encouraging the use of more environmentally appropriate chemicals and the green chemistry research necessary to develop them.
- Regulation. Government regulations can play an important role in driving innovation. An example is government agencies using existing or new legislation to ban specific chemicals in ways that open markets for safer substitutes.

IMPLEMENTATION OF CHEMICAL POLICIES WITHIN STATES: COMPETENCIES AND INSTITUTIONS

States may choose to adopt any of a different number of elements of chemicals policy reform. Any option will create needs for technical competencies and agency capability. Kyle (see Module 6, Kyle) explains what is required for administrative implementation of policies adopted.

The adoption of new chemicals policies will require varied capabilities and related competencies in the institutions charged with implementation. While the exact mix will depend on the policies adopted, capabilities likely to be needed are to: 1) keep track of information; 2) obtain and assess data; 3) disseminate and translate information and judgments for relevant audiences; 4) make decisions about warnings, substitution, controls, use restrictions, or phase-out of chemicals; 5) enforce required policy elements or decisions; develop regulations, directives, procedures, and protocols; and 6) provide technical assistance.

State governments have a variety of options available in:
- Keeping track of information. States will need resources for "knowledge management." Information systems will be used for chemical tracking and sorting and will need to integrate hardware, software, and human elements in a design that meets the needs for data and analysis of individuals and institutions. Existing data systems can provide examples for certain pieces of information tracking. The Chemical Abstracts Service, for example, provides a model for identification of chemical compounds by providing unique identifiers. This is important because nomenclature used for chemical compounds is not standardized, and there are often several synonyms for a single substance.
- Obtaining and assessing data. Strategies to acquire quality data can include overseeing laboratory operations through a certification or accreditation process or by requiring verification. In this respect states will need to identify sources and types of information they will accept. States will likely need to develop **capacity to interpret data** as well as collect it. For data assessment, **the objective is to synthesize information produced in a standard way that allows comparisons across chemicals.** Some data assessment models are available from the EPA and international health and science organizations, and other options exist as well. An example is to standardize testing requirements by using designated protocols (including defaults in the absence of data). This would help to reduce burdens

and facilitate faster decision-making. As testing and assessment methods are currently oriented toward finding chemicals that pose risks, new approaches designed to identify and assess chemicals of low or no concern (safer alternatives) will be needed.

- Disseminating and translating information and judgments for relevant audiences. Providing meaningful and useful information to chemical "publics" has not received the attention it deserves. When state policies call for action by consumers or product users, then characterizing, translating, and disseminating information take on even greater importance. Generally, consumers are more interested in products than in ingredients. Labeling requirements for products is one example that may help.
- Making decisions about warnings, substitution, controls, use restrictions, or phase-out of chemicals. Government agencies may be called upon to make many different kinds of decisions as part of chemicals policy programs including: 1) reporting uses of chemicals included under the scope; 2) providing data and information about chemical hazard traits; 3) developing chemical use management or use reduction plans; 4) conducting monitoring or biomonitoring; 5) adhering to use restrictions or phase-out; 6) providing warnings or labels; and 7) reporting information about hazard traits. Such decisions will usually specify who must act, what the required actions are, and the consequences of not acting.
- Enforcing required policy elements or decisions. The states must develop requirements, regulations, protocols, and procedures that implement policy options, including inspection, verification and enforcement. An example is administrative penalties typically involving fines or revocation of authorizations, particularly when these rise to the level of achieving deterrence.
- Providing technical assistance. As has occurred with pollution prevention, some approaches to chemicals policy may incorporate a significant emphasis on providing outreach and technical assistance. Technical assistance can be a cost effective means to convey information and change practices. States often have close working relationships with businesses and are positioned to offer technical assistance so as to change business practices.

The type of institution to address chemicals policy is also a consideration which has received inadequate attention in the past. These choices tend to vary from place to place. Efforts to structure institutional forms for chemicals policy implementation can draw from various models:

- Creating a single-purpose chemicals agency;
- Developing a program in an existing public agency;
- Creating a hybrid organization that may combine elements of both public agencies and research organizations;
- Networking entities; and
- Multi-state collaborative approaches.

In any of these approaches transparency, accountability, and expertise are critical to the success of the institutional arrangement. Partnerships with universities and other institutions may help with the latter as is the case with the Massachusetts Toxics Use Reduction Institute.

Finally, focused attention on funding is essential to successful state policy. In an age of limited state budgets, a well designed and approved policy will not function without adequate revenue sources. Two principal options exist for funding state programs. One is to appropriate funds from the general fund supported by the overall revenue stream of a state. The second is to create specialized fees or revenue streams specifically to support implementation costs. This is the case with regards to the Massachusetts Toxics Use Reduction Act, where fees assessed on toxic chemicals fund the regulatory and technical support programs.

APPLYING THE CHEMICALS POLICY OPTIONS TO EMERGING TECHNOLOGIES AND MATERIALS: ADAPTATIONS AND CHALLENGES

The final section (see Module 7, Hansen and Rejeski) applies the policy alternatives template for control of risky chemicals to emerging technologies, many of whose hazards are still unknown. Scientists are starting to investigate them. The leading emerging technology used as an example in the comparison is **nanotechnology**, in which the current highest exposures seem to occur when the material takes the form of free particles for workers and particles suspended in liquids or creams for consumers. Throughout the comparison, numerous specific cases are cited. The authors find that indeed, many of the same tools and approaches used in chemicals regulation (outlined in this volume) constitute useful and productive applications when used to gauge the risks of emerging technologies. However, they cannot stand alone. Which options are the best choices in a particular situation will depend on the potential adverse health and environmental impact of the emerging technology in question.

Although many of the issues addressed and the policy options outlined in this module seem most appropriate to implement on a federal level or even a global level, there is a lot that local and state government can do. Action at the state level also sends strong signals:

- Local and statewide regulatory actions. An example is the moratorium implemented in the late 1970s on recombinant DNA research in Cambridge, Massachusetts.
- Requiring environmental health and safety (EHS) information. An example is the city council of Berkeley, California, which has pursued this approach on nanomaterials. They have issued an ordinance requiring manufacturers to disclose various information about the properties of their materials, production facilities, state of EHS research, and their EHS control measures in force.
- Requiring active expert and stakeholder deliberation over a longer period of time. This approach is currently being pursued in Cambridge, Massachusetts, in decisions about nanomaterials.
- Promotion of research into emerging technologies. The promotion of biofuel and stem cell research in California, for example, provides a huge push for research and development of these emerging technologies.
- Formation of interstate collaborations. An example is the New England Climate Coalition dedicated to achieving global warming pollution reductions in the region.

CONCLUSION

This report outlines a range of options to help reshape and reorient chemicals management policy at the state level. The options outlined in the seven modules of this report provide tools and examples of strategies to gather and share information through supply chains; facilitate more effective prioritization and action on chemicals; promote assessment and application of safer alternatives to problematic chemicals; and support research and development of products based on green chemistry. The diffusion of these policy options will help make the states major actors in developing the protective apparatus against and public consciousness about chemical risks that are so needed for health and safety, the environment, and economic development that can sustain Planet Earth.

INTRODUCTION

Reforming State-Level Chemicals Management Policies in the United States: Status, Opportunities, and Challenges

KEN GEISER AND
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It is a propitious time for states to address chemicals policy reform; what critical issues must states consider to successfully implement these policy changes?

During the last several years, there has been increasing public concern about toxic chemicals in everyday products — lead in toys imported from China, flame retardants in computers and furniture, plasticizers in consumer products, and so forth. Scientific studies also are revealing new evidence of the build-up of some chemicals in ecosystems and in our bodies and new findings linking exposures to hazardous chemicals to health effects ranging from cancer to asthma to learning disabilities. These problems demonstrate a failure of both chemical design and responsibility that is driving a new movement for chemicals policy reform in some countries, at the international level and, more recently, among the states in the United States.

There has been little federal initiative in the United States on reforming chemicals management policies for well over two decades. As has historically been the case, states are beginning to fill the holes in federal leadership; debates about chemicals policy reform measures are taking place in at least eight states. We are encouraged by these new efforts at the state level. While some aspects of chemicals policy are best carried out at the national level, other functions can be managed effectively at the state level. In addition, options that might be best located at the federal level can be piloted and developed at the state level, providing valuable models and lessons when Congress or a new administration chooses to engage a process for reforming federal chemicals management policies.

In designing reforms, it is critical to understand the options available — regulatory and non-regulatory and their pros and cons. The purpose of this report is to outline options, provide background, and suggest examples of how states can exert leadership in developing chemicals policy reforms. In essence, this report provides policy foundations for modernizing chemicals policy at the state and ultimately federal levels. It can serve as a resource guide for state and federal policy-makers and other stakeholders who want to engage in dialog about updating chemicals

policies. By providing examples of how some options have been implemented in the past, the report demonstrates that reforms — while challenging — are feasible. Many of the options outlined in this report will require new collaborations, technical capacity, and ways of working. The challenges should not hinder forward movement — agencies are often challenged to implement new policies and processes — but rather be seen as an opportunity to improve chemical safety into the future.

This module provides context for the six "modules" or elements of chemicals policy reform detailed in this report (and described below) and some of the critical issues that must be addressed so that reforms can be implemented successfully at the state level. A seventh module examines how these elements of chemicals policy reform can be applied to emerging technologies and materials. There is a unique opportunity now, given reforms in other locations (for example, the European Union's new Registration, Evaluation, and Authorization of Chemicals (REACH) legislation, outlined below), to modernize state chemicals policies in the United States. But to take advantage of this opportunity and ensure successful progress toward safer chemicals and products, policies must be visionary and far reaching as well as pragmatic and implementable, and they have to respect the current situation of state budgets and agency capacities. Collaboration among states to share efforts and resources will be critical. Ultimately, the most effective reforms will take place at the federal level but actions by several states (and other stakeholders) can serve as an important impetus for federal action.

The module sets a vision for policies to reduce hazardous chemicals in the products we buy and in the places we go. It notes the many opportunities and possibilities and progress that have been made already. It discusses challenges of state-level action that must be addressed in any reform effort. Following an overview of some of the successful examples driving reform of chemicals regulations, we outline the current status of chemicals policy in the United States as well as some of the limitations in current policies.

SETTING A VISION FOR REFORM

While discussions about reforming the way society regulates hazardous chemicals in production processes and products are often contentious, most stakeholders share some common goals. For instance, most would agree with the "Generational Goal" of the 2002 Johannesburg World Summit on Sustainable Development:

"Renew the commitment…aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment…which says that threats posed by toxic chemicals should be eliminated within one generation." (*http://www.un.org/jsummit/html/documents/summit_docs.html*)

This goal encourages creative thinking about the design of a future chemicals economy that solves the problems of the past while stimulating future innovation for safer chemicals and products. Some of the practical results of achieving such a goal could include:

- Businesses and industries that are innovative, versatile, and competitive;
- Products that are safe, functional, and highly valued;
- A natural environment that supports the health and well-being of children, adults, wildlife, and ecosystems; and
- Good, healthy jobs in sustainable industries.

Ultimately, a sustainable chemicals policy will require that these elements be integrated into the very fabric of government, industrial, and consumer decision-making and that environmental and health considerations become as important factors in chemical and product design as cost and functionality. As such, chemicals policy should be seen as part of a competitiveness or economic development issue, important to jobs, health, and economy.

Defining Chemicals Policy

Chemicals policy is a broad term which often is used interchangeably with terms such as toxic substances policy, chemicals management policy, and sustainable chemicals management policy. We view chemicals policies as comprehensive, integrated, and prevention-oriented policies designed to achieve the development and use of less or non-hazardous and sustainable chemicals in production systems and products.

Six general features of chemicals policies are:

- Policies should take a comprehensive and integrated approach to all chemicals. Focus data collection and risk management efforts for a wide range of substances (not just restrictions on single substances — also called toxics policy).
- Take a tiered approach to the treatment of chemicals as discrete entities, categories (such as persistent and bioaccumulative toxics), or groupings (such as chlorinated solvents or brominated flame retardants), not simply air, water, or workplace emissions.
- Regulate chemicals on the basis of their inherent toxicity (hazards) and uses (in manufacturing and products), functions, and potential exposures throughout manufacture, use, and final disposal. By focusing on intrinsic hazard, opportunities to reduce the overall lifecycle impacts of a chemical become more possible.
- Establish processes for rapid chemical assessment and prioritization, including sharing information about chemicals, their properties, uses, exposures, effects, and movement through commerce and the environment.
- Establish processes for replacing dangerous chemicals with safer alternatives — "substitution." Special attention is given to the analysis of substitutes and to the development of methods for evaluating alternatives to those substances considered worthy of avoiding so as to assure that substitutes are reliably safer.

- Move toward greener chemistry and safer product design through the promotion of research, innovation, and capacity-building.

Ideally, chemicals policies should be viewed in a holistic and integrated context — they should ensure protection of worker, community, and consumer health while stimulating development of safer and cleaner production systems, materials, and products.

Chemicals policy encompasses a large number of elements, including:

- Regulatory and voluntary measures, such as those that obtain information on the properties and uses of chemical substances; ensure information is transmitted to users of the chemicals; restrict certain chemicals or uses; or stimulate substitution of problem substances.
- Policies within companies for determining what chemicals are used and how they are used.
- Fiscal policies, such as taxes on certain substances and financial responsibility measures.
- Educational and labeling initiatives.
- Research, development, and technical support for safer chemical products.

Chemicals policy for the purpose of this report relates to industrial chemicals used in manufacturing processes and incorporated into products, not including pesticides and pharmaceuticals. In most countries, pesticides and pharmaceuticals are regulated separately from industrial chemicals, even though there may be some overlap in the particular substances. Further, some product categories, such as cosmetics and sometimes toys and other consumer articles, tend to be regulated under food and drug laws or consumer product safety laws. In the United States, for example, cosmetics are regulated under the Federal Food, Drug and Cosmetics Act (implemented by the Food and Drug Administration) while toys tend to be regulated under the Consumer Product Safety Act (implemented by the Consumer Product Safety Commission). This happens in part because the Toxic Substances Control Act (TSCA) requires that EPA refer risk reduction measures that can be achieved through other statutes to the agencies that implement them. Nonetheless, it makes sense for state-level chemicals policies to integrate different product categories, particularly in the areas of alternatives assessment and chemical use data collection. Since chemicals have intrinsic hazard characteristics regardless of use, it would be effective to include categories such as cosmetics and toys (and possibly household use of pesticides) under chemicals policy efforts.

PROGRESS TO DATE IN REFORMING CHEMICALS REGULATION AND MOVING TOWARDS SAFER CHEMICALS

There are many successful examples of reforms to chemicals regulation at the state, international, and corporate levels that provide experience and lessons in efforts to design new policies. This section outlines some of the successes to date.

Regional Policy Efforts

Important examples of regional chemicals policy efforts have occurred in the United States.[1] For example, the New England states have worked closely on issues related to mercury since the 1990s. Perhaps the strongest example of regional policy is in the Great Lakes area. From the mid-1970s until the early 1990s, a multi-stakeholder discussion on chemicals policy occurred in the Great Lakes region. In its 1992 and 1994 Biennial Reports, the United States-Canada International Joint Commission (IJC), which provides expert advice about Great Lakes water quality, recommended phasing out releases of all persistent and bioaccumulative chemical substances. Unfortunately, ambitious reduction goals and IJC recommendations have not led to broad policy reform by Canada, the United States, or the Great Lakes state governments. This regional chemicals policy vision has been stalled by a lack of political will but possibly could be revived given recent Canadian initiatives on chemicals management.

State Policy Efforts

Noting the slow pace of federal government regulations on hazardous chemicals, various states have acted on their own.[2] During the early 1990s, several states passed pollution prevention and hazardous waste reduction laws focused on industry education, outreach demonstration projects, and on-site technical assistance services. Today, Massachusetts and New Jersey have highly successful programs that combine voluntary business assistance with mandatory chemicals use reporting and pollution prevention planning regulations. One of the most successful state laws addressing toxic substances in products is the California Safe Drinking Water and Toxic Enforcement Act of 1986 (or "Proposition 65"), which prohibits businesses from discharging chemicals that have carcinogenic or reproductive toxicity effects into sources of drinking water. Under the law, the state government is required to maintain a list of chemicals known to the state to be carcinogenic or reproductive toxicants. Businesses must provide clear warnings to individuals exposed to these chemicals in products either manufactured or sold by them. Citizens are allowed to sue companies for failure to properly warn the public.

During the last several years, advocates and policy makers in several states — particularly Washington, Maine, California, Oregon, Michigan, and Massachusetts — have moved forward with chemicals management policy reform efforts. More than 20 states, including New Hampshire, Vermont, Maine, Massachusetts, Rhode Island, Oregon, and Connecticut, have passed legislation to phase out the use of mercury in various consumer products.[3] In the summer of 2003, California passed a bill that prohibits the use of two polybrominated diphenyl ethers, common flame-retardants, in commercial products. Several additional states have since enacted laws phasing out the use of these same flame-retardants. Other states have proposed or passed legislation restricting phthalates and bisphenol-a in children's products. While most state initiatives have focused on restrictions on single chemicals, major chemicals policy reform bills are likely in the near future, such as the Act for a Healthy Massachusetts, which builds on the successful Toxics Use Reduction program and would require the development of alternatives assessments and substitution plans for ten priority chemicals of concern.

Some governors have advanced chemicals management policies even in the absence of legislation. Several states and localities have initiated voluntary and mandatory programs to reduce the use of persistent bioaccumulative toxics (PBTs). In 1998, Washington State approved a statewide policy for eliminating pollution caused by PBTs. The program designated nine PBTs for reduction, and included thirteen more in the "PBT Working List" of chemicals for future action plans.[4] The state's Department of Ecology is implementing the program through monitoring, public education and outreach, research, and targeted procurement practices. In 1999, the governor of Oregon issued an executive order directing state officials to achieve zero discharge of persistent chemicals by 2020.[5] In 2006, the governor of Maine published an executive order requiring a thorough assessment of the state's chemicals management policies[6] and Michigan's governor used her executive powers to call for the development and promotion of green chemistry in that state.[7] The state of California has a Green Chemistry Initiative[8] designed to promote a dialog on chemicals policy reform in that state. Other states and localities have established procurement policies that prohibit the use of certain chemicals and encourage the purchasing of others in state and municipal government contracts.

International Successes in the Reform of Chemicals Regulations

But there are important global initiatives as well that are creating the conditions and the impetus for modernizing chemicals regulation. Most importantly perhaps are policy reforms occurring in Europe, but others happening at the global level and within industry also provide strong incentives for modernization in the United States.

During the last two decades, European countries have been particularly active in pioneering new chemicals management policies, in part due to limitations in European Union-wide policies.[9] The Nordic countries — Sweden, Denmark, and Norway — have long set the standards for international chemicals policy debates in Europe, in an attempt to stimulate regional policy. Their concerns about chemicals involve the contamination of waterways caused by persistent and bioaccumulative pollutants, as well as chemical exposures from everyday products. With a focus on hazardous chemicals in products, the Nordic countries have implemented policies that involve rapid screening processes, publication of "lists of chemicals of concern," phase-out of harmful chemicals, and the development and adoption of safer products through clean technologies and chemical substitution.

Other countries also have developed innovative programs.[10] The Dutch government established a Strategy on Management of Substances in 1998 as a multi-stakeholder process to address hazardous substances risks. This system placed responsibility on industry to undertake a "quick-scan" analysis of all chemicals for health and environmental effects. In 1999, the United Kingdom issued a voluntary chemicals management policy proposal that sets targets for chemical testing and risk reduction decisions and establishes a Stakeholder Forum to advise the government on its chemicals policy. The Stakeholder Forum developed a set of criteria to enable rapid identification of chemicals of concern, leading to implementation of risk management strategies proposed by industry. Many of these European country initiatives were partially or fully discontinued with the passage of new European-wide chemicals policy legislation (see below).

The Canadian Environmental Protection Act of 1999 requires that all existing substances on the national Domestic Substances List (DSL) be sorted by category by the government of Canada to determine which need further attention.[11] Using information from Canadian industry, academic research, and other countries, government scientists at Health Canada and Environment Canada worked with various business and non-governmental partners in applying a set of rigorous tools to each of the approximately 23,000 chemical substances on the DSL. In September 2006, Canada completed its categorization exercise and the information is now available to the public. The Canadian government is using the list to focus attention on the chemical substances of highest priority for assessment or further research and those in need of controls to protect human health and the environment.

In December 2006, after seven years of drafting and debate, the European Union adopted a far-reaching new regulation on chemicals management for its 27 member states.[12] The overarching goals of this new policy known by the acronym REACH involve the protection of health and promotion of a non-toxic environment, while preventing fragmentation of the internal European market, avoiding barriers to trade, and enhancing the innovation and competitiveness of European industry.

The new policy requires that all chemicals produced or imported into member states at one metric ton per year per producer or importer (some 30,000 substances) must be registered with a new European Chemicals Agency in order to remain on the market.[13] For chemicals of ten metric tons per year or more, registration will require basic ecological and human toxicity data, which will be tiered based on production volume as well as the development of a Chemical Safety Report which will provide exposure and risk management information for all uses of the chemical along supply chains. Registrants of substances produced in larger quantities will be required to provide a justification for waiving more extensive tests. In addition, chemicals of particular concern will be considered for undergoing an evaluation process conducted by the European Union countries that can result in proposals for accelerated risk management measures, including requirements to obtain use-specific authorizations, and, where risks cannot be adequately controlled, restrictions and bans on the use of the substances. Chemicals of greatest concern, such as known or suspected carcinogens, reproductive toxicants or mutagens; persistent, bioaccumulative toxics; and very persistent, very bioaccumulative chemicals (approximately 1,400 chemicals), will be identified as candidates to undergo a government authorization process to continue their use (a reverse onus as in drug regulation). Authorization will be made on a case-by-case basis considering socio-economic impact, necessity, health and environmental risks, ability to control exposures, and the economic and technical feasibility of alternatives.

Ultimately, REACH will significantly affect international chemicals markets, forcing information to more effectively flow up and down supply chains and resulting in the "withdrawal" of many chemicals from the market due to health concerns or simply the economics of having to develop testing data and safety information.

The passage of the REACH regulation follows the recent adoption of two other European Union directives affecting toxic substances: the Directives on Waste from Electronic and Electrical Products (WEEE) and Restrictions on Hazardous Substances (RoHS) which limit the use of certain chemicals in electronic products; and the Cosmetics Directive which restricts carcinogens, mutagens, and reproductive toxicants in cosmetic products. Both have had important global implications[14] — particularly in the United States for manufacturers wishing to export to Europe — and a positive influence on U.S. state-level policy development efforts. Several states, such as Massachusetts where European exports account for a large percentage of global exports, have initiated dialogs with the electronics sector to help prepare them to go beyond WEEE and RoHS.

Other chemicals management policy drivers exist at the international level.[15] They include the Stockholm Convention, which establishes a legally binding means to address threats to health and the environment caused by persistent organic pollutants (POPs). This agreement brokered by the United Nations Environment Program in 2001 establishes an international production phase-out of twelve substances, including already restricted pesticides; polychlorinated biphenyls; and dioxins and furans. It also provides for financial and technical assistance to developing countries in inventorying and destroying existing stocks of POPs; international research and monitoring of POPs; and a "precautionary" process to add new POPs to the convention's list. New chemicals currently being discussed as candidates include polybrominated diphenyl ethers, lindane, and perfluorinated compounds.

The United Nations has undertaken several other initiatives to reduce risks from the global circulation of chemicals.[16] The Regionally Based Assessment of Persistent Toxic Substances builds on the Stockholm Convention to establish a comprehensive regionally based assessment of the damage, threats, and concerns posed by persistent toxic substances and to evaluate and agree on priorities for intervention. The Rotterdam Convention on Prior Informed Consent (PIC), adopted in 1998, facilitates information exchange about hazardous chemicals, their international trade, and restrictions on their use. The Intergovernmental Forum on Chemical Safety (IFCS), a United Nations-sponsored effort of 120 countries and non-governmental organizations, provides policy guidance and makes recommendations on chemicals classification and labeling, pollution prevention, and hazard reduction. Finally, the United Nation's Strategic Approach to International Chemicals Management is now viewed as the coordinated effort to strengthen chemicals management globally.

Business Successes in Moving Toward Safer Chemicals

While government activities to reform chemicals regulations are critical, some very important market successes also are creating the impetus for reforms. As a result of concerns about the health effects of chemicals, customer concerns, or catastrophes involving their products, many leading companies are beginning to exert their own market influence to demand safer chemicals in their supply chains.[17] In some cases, large retailers, such as Wal-Mart, H&M, Boots, and Marks and Spencer, have instituted chemicals policies, including restricted substances lists, with which their suppliers

must comply. This also is occurring in the health care sector, where various hospital organizations and health care purchasing groups are issuing lists of restricted substances. Many leading manufacturers ("downstream users of chemicals") are developing processes to prioritize chemicals of concern and assess safer alternatives. In some cases, there are sector-wide guidelines on restricted substances, such as in the footwear and apparel industry. These firms see the benefits in avoiding problem chemicals as well as investing in the implementation of safer alternatives. Such actions of large firms have the potential to create large-scale market changes in the absence of concrete regulations. Business interest in advancing the application of safer chemicals and products has led to the formation of new organizations such as the Green Chemistry and Commerce Council, a network of leading-edge companies that hopes to work with multiple stakeholders in creating conditions for safer products.

LIMITS OF CURRENT CHEMICALS MANAGEMENT POLICIES[18 19 20 21]

The initiatives outlined above are direct responses to the lack of adequate knowledge and control of hazardous substances in commerce — in production and everyday products. For many years, there has been widespread public concern about human exposure to toxic substances and the lack of information on how these exposures might affect health. Concerns about the health effects of occupational and environmental exposures to mercury, lead, arsenic, asbestos, and chlorinated solvents have a long history. More recently, concerns about phthalates and brominated flame retardants have been prominent. During the last decade, public disclosures in the United States and Europe about contaminated food, biotechnology, increasing health threats such as cancer and asthma, and pollution of lakes, rivers, and coastal waters have led to a growing recognition of the inadequacies of current chemicals management systems to protect human health and the environment.

A recent report on chemicals policy in California referred to three key failures of chemicals management policies to date: the Data Gap, the Safety Gap, and the Technology Gap.[22]

The Data Gap

During the last half century, thousands of chemical substances have been developed and put into commerce, often with little information about or consideration of their environmental or health implications. While we know a lot about some chemicals, for a large percentage of chemical substances, there is still little information on their health implications, and more importantly their exposures, and how they are used throughout supply chains (and the economy). For example, we have little information on what chemicals are used in what products, how the chemicals can lead to consumer exposures, and what potential alternatives might exist. Studies conducted by both the U.S. Environmental Protection Agency (EPA) and the European Chemicals Bureau in the late 1990s highlighted the serious lack of information about the toxicity of some of the most frequently used chemicals on the market today.

Initial research by the EPA found that less than ten percent of the approximately 2,800 high production volume chemicals (those produced over one million pounds per year) had a basic set of publicly available toxicity information. During the last decade, the chemical industry has worked with the EPA through the High Production Volume Chemical Challenge Program to fill these gaps.[23] However, significant information remains missing on chemicals produced in smaller volumes and those in mixtures of chemicals. Without adequate health and environmental effects data, it is difficult to assess the risks of chemicals, set science-informed priorities, or feel confident that chemical substitutes are safer than chemicals of concern. Without data on exposures, uses, and supply chain flows, it is impossible to effectively manage chemicals or understand their environmental fates. Unfortunately, under the current system while data are collected, the lack of evidence of toxicity is often misinterpreted as evidence of safety, and the status quo — allowing exposure to continue — is maintained. Collecting more data — on chemical toxicity, human body burdens, exposures, and uses — is critical to understanding how chemicals can affect human and ecosystem health as well as to effective chemicals management; however, study alone will not prevent harm.

The Safety Gap

Even when basic toxicity information is compiled, it is fed into a regulatory system in which the burden rests on government agencies to conclusively demonstrate the risks that each individual substance poses to health or ecosystems before preventive action can be taken. This scenario developed in part because under the federal TSCA all chemicals on the market when the law came into effect in 1980 (about 99% by volume of chemicals on the market today) were assumed safe until it was demonstrated that they presented an "unreasonable risk." Demonstrating an unreasonable risk means that the EPA must present strong toxicological evidence (using quantitative risk assessment, a tool which is both expensive and time consuming), as well as show that the benefits of regulation outweigh the risks of not regulating, and that the least burdensome means to reduce risk was chosen.

The regulation of chemicals in the United States is split between different federal agencies and divided among divisions even within the EPA. The agency focus has been disjointed and reactive in nature, often responding to well-established problems by managing or reducing exposure to individual harmful chemicals rather than stimulating the development of safer and cleaner chemicals, production systems, and products. During the 1970s, the U.S. Congress enacted a suite of broad regulatory statutes to control chemical releases to the air, water, and land through facility release permits. These media-focused waste and pollution control regulations, plus consumer product safety, pesticide, and occupational health laws, have had some successes in limiting exposures to toxic substances from manufacturing, use, and disposal processes, but they do not address in any integrated manner the entire lifecycle of chemicals from production through disposal.

Indeed, there is growing recognition that chemicals used in everyday products — which can be widely dispersed in the environment and pose significant risks to humans and ecosystems —have been largely ignored under current chemicals regulations. Our current laws were written at a time when chemical concerns were related to large-scale exposures from a few manufacturing

firms and very pronounced health effects (acute toxicity, cancer). We are now learning that smaller exposures at critical windows of development can result in often subtle but important adverse health effects. Rather than large volumes of hazardous chemicals generated by a few large industries, today we find small amounts of toxic chemicals released from a wide range of products ubiquitously distributed about our homes and workplaces. Current laws are inadequate to address these kinds of exposures.

The Technology Gap

There is little incentive under the current system to use safer chemicals if the more dangerous ones are not regulated. While the EPA has undertaken significant steps in working with industry to design safer chemicals and products, through its Design for Environment and Green Chemistry efforts, these programs are woefully under-funded and marginalized. For example, the EPA has provided tools to industry to more effectively integrate health and environmental concerns at the design stage of chemicals, but few chemicals that have come through the agency's new chemicals review process have gone on to reach market prominence. Indeed, even less funding is available for the research and development of safer chemicals and products at the state or federal level. Only when governments provide the needed regulatory and market drivers can the development of safer chemicals become the norm rather than the exception.

LIMITATIONS IN U.S. FEDERAL CHEMICALS POLICY

Many of the early federal environmental protection statutes contained bold and far-reaching chemicals management goals and policies, such as the Clean Water Act's goal of clean water bodies by 1986. However, in practice, many of these bold goals have never been attained.

In particular, TSCA, enacted in 1976, established programs for addressing existing chemicals on the market prior to 1980 and new chemicals entering the market since then.[24] The new chemicals program provides a 90-day period (with a potential 90-day extension) for the EPA to review applications for new chemicals.[25] While the agency uses its authorities to discourage new harmful substances, it is hampered by the short time period and by having no minimum set of pre-manufacture data requirements. As noted above, even less authority exists for addressing the risks posed by existing chemical substances, which constitute the vast majority of chemicals by volume on the market today. These chemicals arguably pose the greatest risk to health and the environment, but the government has only been able to use its authorities a few times to restrict dangerous chemicals given the high burden of evidence required and the resource investment needed to fulfill requirements. The evidentiary bar is set too high for the majority of conventional chemicals of concern (carcinogens, reproductive toxins) and beyond reach for chemicals that pose newer, more subtle concerns, such as neurotoxins, endocrine disrupters, and allergens. Even chemical testing requirements are hindered by burdens placed on the agency before testing is required. Since a federal appeals court in 1991 struck down the 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.

These limitations of TSCA have been broadly described elsewhere over the last twenty years.[26] Despite the limitations, there has been little momentum to reform or update TSCA. As a result, the EPA has been forced to rely on voluntary challenge programs with varying degrees of success, such as the High Production Volume Challenge, to address gaps in chemicals regulations and limits on the agency's ability to implement its authorities.

Despite the limits of TSCA (and given increased attention and interest in voluntary pollution prevention activities), the EPA has initiated, through its Office of Pollution Prevention and Toxics, a number of voluntary outreach, education, and demonstration programs to encourage industry to reduce hazardous chemicals use, develop cleaner, safer chemicals, and design cleaner products. They include various sector-based initiatives, such as the Common Sense Initiative and the Cleaner Technology Substitutes Analysis program, as well as the Design for Environment Program. The agency also has programs to encourage industry to develop better data on chemical risks, such as the High Production Volume Challenge and the Voluntary Children's Testing Program. While useful tools for chemicals management, these programs have been limited by the lack of a regulatory backbone to ensure broad application.[27]

OPTIONS FOR REFORMING CHEMICALS REGULATION AT THE STATE LEVEL

Even a modest overview of the current state of chemicals management policy in the United States reveals the significant disparity between the public concerns about hazardous chemicals and the limited and disjointed policy infrastructure for addressing those chemicals. *The public expects and public health requires that toxic and hazardous chemicals should be managed safely and responsibly.* However, neither government nor the regulated industries and institutions can meet these expectations within the current policy framework. There is a critical need for new directions for chemicals management policy in the United States. If history provides lessons, it is likely that any reforms in chemicals regulation will likely occur first at the state level. State- level discussions on chemicals policy reform have evolved in part due to the lack of federal leadership, concerns about the build-up of chemicals in the environment and their impacts, and advocacy campaigns for change. States have been the laboratories of innovation in environmental policy in part because the impacts of chemicals are local in nature and greater stakeholder dialog tends to occur locally.

The Elements of Reform

New policy directions must take into consideration the scale of the chemicals market and the paucity of appropriate information on thousands of existing chemicals that are widely used in commercial products and industrial production. There is a clear need to shift the burden for generating this data from the government to the manufacturers and users of these chemicals.

To facilitate it, much more attention should be given to the flow of information, from supplier to chemical user, from chemical user to customer, from chemical processor to the concerned public, and from the chemical industry to the government. The scale and current uncertainty involved in continued chemicals use and public exposure requires a more judicious and cautious approach, and government agencies must be liberated from the long, costly, and contentious risk assessment and cost/benefit procedures that currently stall effective risk reduction efforts. We must invest more heavily in classifying and categorizing chemicals so as to overcome the need to spend years addressing each substance singly and enhance the focus on alternatives assessment in policy, the evaluation of chemical, process, or functional alternatives that can replace a chemical of concern. Finally, there is a need to focus on the creation of new safer and more environmentally compatible chemicals that can serve as substitutes and replacements for chemicals whose use has been continued because there are no effective alternatives. There is substantial need for good science here — science for understanding toxicity and risk and green chemistry science for developing alternatives. There also is a need for more substantial political will and a more serious political commitment to ensuring a sustainable future.

A major restructuring of the nation's chemicals policies must be composed as a comprehensive and integrated framework to avoid the current problems caused by diverse and ill-coordinated responsibilities. However, it is possible to consider a range of policy options that could be adopted as interim steps. Many potential policy options could be adopted at state, local, or regional levels as experiments and pilots to demonstrate effectiveness and potential problems before launching broad national reforms.

This collection of policy analyses presents options for policy reform with the conviction that state and local governments can play a significant role in promoting national policy reform. To make dialog, understanding, and action on chemicals policy reform more manageable, we have divided reform efforts into six "modules." Comprehensive reform of chemicals policy would include at least some elements of each. In each module, the pros and cons and examples of a range of voluntary and regulatory policy options are presented. The six modules address:

- Testing and Information Generation — options to ensure generation of adequate data on chemical toxicity, use, and exposure.
- Information in the Production Supply Chain — options to ensure that data are shared throughout supply chains, including the public, to enhance the abilities of chemicals users to make informed decisions leading towards safer chemicals and products.
- Screening, Assessment, Prioritization and Decision-Making — options to enhance the ability of agencies to more rapidly screen, prioritize, and make decisions on a broader range of substances.
- Chemical Substitution and Use Reduction—options to enhance toxic chemicals use reduction and substitution of problems by safer alternatives.
- Innovation and Green Chemistry — options to encourage research, development, and adoption of safer chemicals and products.
- Program Administration and Implementation — options and considerations for effective implementation of chemicals policy reform.

Given growing concerns about the health and safety implications of nanomaterials, the current lack of federal government oversight, and the fact that industrial use of emerging materials tends to be regulated like industrial chemicals (for example, industrial uses of biotechnology), a last module explores how policy options in the six modules could be effectively applied to the regulation of emerging materials, with particular emphasis on nanomaterials.

The goal of this report is to provide a menu of options that states, regions, or the federal government can choose from to implement reforms. Many of the options could be implemented at the state level (such as alternatives assessment requirements) while some (such as toxicity testing) would be most effectively implemented at the federal level. The module on Program Administration is particularly important, given the size of the reforms envisioned and the fact that to be successful, a program must be implementable, enforceable, and accountable.

THE CHALLENGE OF REFORMING CHEMICALS MANAGEMENT POLICIES AT THE STATE LEVEL

The broad overhaul envisioned here is a significant undertaking. Many policy instruments should be considered, ranging from new legal authorities to restrict chemical use, to new funding for well-targeted research, new programs to encourage the development of safer chemicals, and new efforts to present data and assure that it reaches key decision-makers in government and business. Even simple bans and restrictions on individual chemicals present challenges in implementation. Policy-makers and other stakeholders must be cognizant of these challenges because a poorly implemented policy with limited results will create skepticism towards government's ability to manage chemicals and hinder future efforts at reform.

Some potential pragmatic challenges to state-level chemicals policy reforms include:

- **Agency resources and capacity.** Most of the chemicals policy options outlined in the six options modules require some level (which can vary widely) of agency implementation. It is a challenge given that many state environmental agencies have had significant budget reductions over the last decade. Resources will be necessary for: developing new databases and data collection systems; chemical review, alternatives assessments, stakeholder engagement, developing guidance documents and technical support, and enforcement. Enforcement is particularly important, since implementation and compliance will depend both on a serious threat of action if a firm does not comply with requirements as well as support measures to help firms. Many activities, such as new data collection schemes, databases, and assessment protocols, may require a large upfront investment to develop the schemes and capacity. For example, if a state wishes to track chemicals in products in the state (including those coming into the state), it will have to develop some type of product registry system, guidance, and enforcement measures — a very large undertaking though not impossible, as the Nordic Product Registers demonstrate.

Capacity is as important as financial resources. Many agencies lack toxicological or risk assessment capacities and others lack strong capacities in pollution prevention and safer chemicals and materials development. Agencies will need adequate capacity to allow implementation of new policies.

While increasing the budgets of agencies — through increased state budget line item funding or some kind of fee structure on chemicals — is an important step, some of these resource and capacity issues could be resolved through greater intra- and interstate collaboration. For example, environment agencies could collaborate with university centers or other agencies (as is the case in Massachusetts under the Toxics Use Reduction Act) to implement parts of reforms, taking advantage of resources within the state. States also could form interstate consortiums, for example, an interstate chemicals clearinghouse to share the costs of developing new data collection systems on chemical hazards and use or to split the burden of undertaking chemical alternatives assessments. There are some models of such collaboration that should be explored.

These capacity issues also refer to companies implementing chemicals policies as well as the ability of stakeholders to participate in chemicals policy reform dialogs. Many small- and medium-sized companies, where the environment director plays many different roles, lack capacity for large-scale data collection and assessment or implementation of alternatives or sufficient market power to demand data from suppliers. As such, technical assistance programs must be a critical component of any reform effort.

- **End-of-life considerations.** Restricting a substance that is widely used in products also will require instituting measures to ensure that the chemical does not end up in the environment at the end of product lifecycles. It will require that policies do not encourage the introduction of these materials into the environment. For example, environmentally oriented recycled carpeting regulations in some states could lead to dispersed reintroduction of polybrominated diphenyl ethers into the environment from recycled foam cushions. The experience with mercury demonstrates that end-of-life collection of problem materials can be accomplished but is not a simple matter. However, particularly for materials that are persistent and bioaccumulative, end-of-life impacts of existing substances subject to restrictions must be considered. The history of clean up of hazardous waste sites provides ample evidence of the need to consider the end-of-life of chemicals and products containing them.

- **Uncertainty and limits of science.** There is still much that we do not know about chemical toxicity, the cumulative impacts of multiple chemical exposures (which are commonplace), and how chemicals are used throughout supply chains. Well-designed chemicals policies will fill these gaps but will not eliminate them. Thus, it is critical that decision-making on chemicals not be paralyzed by uncertainty but recognize that uncertainty will always be an inherent aspect of chemicals management efforts. Designing policies that are adaptable to new knowledge, assure an ability to make rapid decisions, and allow for follow-up to

decisions is important. Research on chemical hazards, exposures, uses, and alternatives should form part of any policy scheme. In some cases though, decisions will have to be made on the basis of less than desirable information, which is where the concept of precaution comes in — making decisions to protect health and environment under uncertainty, while stimulating innovation in safer chemicals and materials.

- **Jurisdictional issues.** To date, chemicals regulations have been implemented through environmental agencies. In some states, however, health departments have played some role in chemicals assessment and management. Lack of clarity about jurisdiction or multi-layered jurisdiction can lead to conflicts whereby chemicals management activities suffer. For example, when concerns were raised about lead leaching from vinyl lunchboxes, both the Consumer Product Safety Commission and the Food and Drug Administration viewed this product as under their jurisdiction (one the outside of the lunchbox and one the inside). Chemicals policies should clearly lay out responsibilities and accountability for different aspects of chemicals policies and how conflicts in jurisdiction should be handled. Ideally, new agencies or divisions within agencies that address chemicals policy would make for a more effective implementation.

- **Holistic thinking.** Since to date chemicals policy has been largely implemented in environmental agencies, there is a chance that concerns about risk trade-offs to workers or consumers or jobs may not be adequately addressed. For example, if an agency is only focused on Persistent and Bioaccumulative Toxics (PBTs) (an environmental hazard), it may restrict one but the alternative may be a substance that increases worker risks (a neurotoxicant). In some communities, acutely toxic chemicals — for example, from a refiner — may be of greater concern than PBTs. As such, thinking holistically about implementing chemicals policy — considering worker, environment, community, and consumer health and a broad range of substances — will help ensure that chemical hazards are addressed in as thoughtful a way as possible.

- **Imports.** Chemicals and products containing chemicals may be manufactured in a particular state. However, they also may be imported into the state from another state or another country. The recent concerns raised about lead in toy imports from China demonstrate the challenge of tracking millions of products from throughout the globe. While states have successfully addressed chemicals management in their manufacturing facilities (for example, in Massachusetts), chemicals in products may present equally important risks to health and environment. Policies will have to establish mechanisms to ensure compliance of out-of-state and global manufacturers with chemicals policy requirements and inspection capacity to ensure compliance. Multi-state collaborations where resources are shared among states may help.

Additional considerations and challenges that must be acknowledged include: harmonization with other laws nationally and globally (for example in labeling requirements); measurability of results (how to know whether policies are effective); transparency of process and decisions; and flexibility to grow to changing conditions.

CONCLUSION

While there are plenty of challenges to implementation of chemicals policy reforms, there are many opportunities at this point in time. Growing public awareness about chemical hazards and limits of current policies, the European REACH legislation, several state-level policy dialogs, the growth of green chemistry and leadership of many in industry make this an opportune time to innovate and experiment at the state level. We need laboratories of innovation to try out new chemicals policies and refine them, new collaborations of states, and ultimately a federal dialog on long-term chemicals policy reform. Reform may not be easy, but we have little choice. The long-term health of our children and planet and sustainable industries and jobs depend on beginning the process of finding solutions today.

ENDNOTES

1 Tickner, J et al. The US Experience in Promoting Sustainable Chemistry. *Environ Science & Pollut Res.* 12(2): p.115-123.

2 Tickner, J et al. The US Experience in Promoting Sustainable Chemistry. *Environ Science & Pollut Res.* 12(2): p.115-123.

3 Northeast Waste Management Officials' Association. *http://www.newmoa.org/prevention/mercury/.*

4 Washington State PBT Policy. http://www.ecy.wa.gov/programs/eap/pbt/pbtfaq.html.

5 Executive Order No. EO-99-13, Elimination of Persistent, Bioaccumulative and Toxic Pollutants. Oregon State Archives, *http://arcweb.sos.state.or.us/governors/Kitzhaber/web_pages/governor/legal/execords/eo99-13.pdf.*

6 An Order Promoting Safer Chemicals in Consumer Products and Services. *http://www.maine.gov/tools/whatsnew/index.php?topic=Gov_Executive_Orders&id=21193&v=Article.*

7 Executive Directive No. 2006-6, Promotion of Green Chemistry for Sustainable Economic Development and Protection of Public Health, *http://www.michigan.gov/gov/0,1607,7-168-36898_40426-153806—, 00.html.*

8 California Green Chemistry Initiative, *http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistry Initiative/index.cfm.*

9 Tickner J and Geiser, K. New Directions in European Chemicals Policies. The Lowell Center for Sustainable Production, 2003.

10 Tickner J and Geiser, K. New Directions in European Chemicals Policies. The Lowell Center for Sustainable Production, 2003.

11 Canadian Environmental Protection Agency Environmental Registry, *http://www.ec.gc.ca/CEPARegistry/.*

12 Fasey, A. REACH is Here: The Politics are Over, Now the Hard Work Starts. *http://www.chemicalspolicy.org/downloads/REACHisHere220307.pdf*

13 Fasey, A. REACH is Here: The Politics are Over, Now the Hard Work Starts. *http://www.chemicalspolicy.org/downloads/REACHisHere220307.pdf*

14 Geiser, K and Tickner, J. 2006. International Environmental Agreements and the Information Technology Industry. In *Challenging the Chip*, Hightower, J; Temple University p 260-272.

15 Tickner J and Geiser, K. New Directions in European Chemicals Policies. The Lowell Center for Sustainable Production, 2003.

16 Tickner J and Geiser, K. New Directions in European Chemicals Policies. The Lowell Center for Sustainable Production, 2003.

17 The Green Chemistry and Commerce Council website; http://www.greenchemistryandcommerce.org/home.php. Also, see Greiner, T et al. Healthy Business Strategies for Transforming the Toxic Economy. Clean Production Action. June 2006.

18 Tickner, J et al. The US Experience in Promoting Sustainable Chemistry. *Environ Science & Pollut Res.* 12(2): p.115-123.

19 Chemical Regulation: Comparison of US and Recently Enacted European Union Approaches to Protect Against the Risks of Toxic Chemicals. US Government Accountability Office Report to Congressional Requesters. GAO -07-825. Aug. 2007.

20 Not That Innocent: A Comparative Analysis of Canadian, European Union, and United States Policies on Industrial Chemicals. Environmental Defense and Pollution Probe, Apr. 2007.

21 Wilson, M et al. Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation. California Policy Research Center, University of California, 2006. Available at *http://coeh.berkeley.edu/FINALgreenchemistryrpt.pdf*

22 Ibid

23 See *www.epa.gov/hpv*

24 Tickner, J et al. The US Experience in Promoting Sustainable Chemistry. *Environ Science & Pollut Res.* 12(2): p.115-123.

25 The Future of US Chemical Regulation. *Chemical and Engineering News.* 85(2): p 34-38

26 See Denison, Richard. 2007. Not That Innocent: A Comparative Analysis of Canadian, European, and U.S. Policies on Industrial Chemicals. Washington, DC: Environmental Defense; Government Accountability Office. 2007. Chemicals Regulation: Comparison of U.S. and Recently Enacted European Approaches to Protect Against the Risk of Toxic Chemicals. Washington, DC GAO-07-825.

27 The Future of US Chemical Regulation. *Chemical and Engineering News.* 85(2): p 34-38

Options for State Chemicals Policy Reform

A RESOURCE GUIDE

This report outlines a range of options to help reshape and reorient chemicals management policy at the state level so that it more effectively protects health and environment while stimulating innovation, and safer chemistry and products. The options provide tools and examples of strategies to gather and share information through supply chains; facilitate more effective prioritization and action on chemicals; promote assessment and application of safer alternatives to problematic chemicals; and support research and development of products based on green chemistry.

This document is available at *www.chemicalspolicy.org/publications.shtml* and *www.sustainableproduction.org*.

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