

Options for State Chemicals Policy Reform

A RESOURCE GUIDE



Lowell Center for
Sustainable Production

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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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Glossary

ASTM	American Society for Testing Materials	JIG	Joint Industry Guide for Material Composition Declaration for Electronics Products
CAAA	Clean Air Act Amendments	KEMI	Swedish Chemicals Agency
CASRN	Chemical Abstract Service Registry Number	MBDC	McDonough Braungart Design Chemistry
CBI	Confidential Business Information	(M)SDS	(Material) Safety Data Sheets
CEPA	Canadian Environmental Protection Agency	NESCAUM	Northeast States for Coordinated Air Use Management
COSHH	Control of Hazardous to Health Regulations	NEWMOA	Northeast Waste Management Officials Association
CMS	Chemical Management Services	NGO	Non-Governmental Organization
CPSC	Consumer Product Safety Commission	NHANES	National Health and Nutrition Examination Survey
CSR	Chemical Safety Report	NIHES	National Institute for Environmental Health and Safety
Deca-BDE	Decabromodiphenyl Ether	NIOSH	National Institute for Occupational Safety and Health
DfE	Design for Environment	NPPTAC	National Pollution Prevention and Toxics Advisory Committee
DEHP	Diethylhexyl Phthalate	NTP	National Toxicology Program
DSL	Domestic Substances List	OBS	Swedish Chemicals Inspectorate Observation List
EEE	Electrical and Electronic Equipment	OECD	Organization for Economic Cooperation and Development
EHS	Environmental Health and Safety	OEM	Original Equipment Manufacturer
EKG	Electrocardiogram	OPPT	Office of Pollution Prevention and Toxics
EPA	Environmental Protection Agency	OSHA	Occupational Safety and Health Association
EPCRA	Emergency Planning and Community Act	OTA	Office of Technology Assessment
EPP	Environmentally Preferable Product	PAIR	Preliminary Assessment Information Reporting Rule
EU	European Union	PBT	Persistent, Bioaccumulative, Toxic
FD&C	Food, Drug and Cosmetic Act	PBDE	Polybrominated Diphenyl Ethers
FDA	Food and Drug Administration	Penta-BDE	Pentabrominated Diphenyl Ether
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act	PIC	Prior Informed Consent
FQPA	Food Quality and Protection Act	PMN	Premanufacture Notice
GHS	Globally Harmonized System for the Classification and Labelling of Chemicals	P2	Pollution Prevention
GMO	Genetically Modified Organism	POP	Persistent Organic Pollutants
HPV	High Production Volume	PRIA	Pesticide Registration Improvement Act
IARC	International Agency for Research of Cancer	Prop 65	The Safe Drinking Water and Toxic Enforcement Act of 1986
IFCS	Intergovernmental Forum on Chemical Safety		
IJC	International Joint Commission		
IMERC	Interstate Mercury Education Reduction Clearinghouse		
IPP	Integrated Product Policy		
IRIS	Integrated Risk Information System		
IT	Information Technology		
ICT	Information and Communication Technology		
IUR	Inventory Update Rule		

PVC	Polyvinyl Chloride
QA/QC	Quality Assurance/ Quality Control
(Q)SARs	(Quantitative) Structure Activity Relationships
R&D	Research and Development
REACH	Registration, Evaluation, and Authorization of Chemicals
RMP	Risk Management Plan
RoHS	Restrictions on Hazardous Substances
SBIR	Small Business Innovation Research
SBTT	Small Business Technology Transfer
SIDS	Screening Information Data Set
SMART	Synthetic Method Assessment for Reduction Technique
STOA	Scientific Technology Options Assessment
SVHC	Substances of Very High Concern
TSCA	Toxic Substances Control Act
TUR	Toxics Use Reduction
TURA	Toxics Use Reduction Act
TURI	Toxics Use Reduction Institute
UK	United Kingdom
USGS	US Geological Survey
vB	Very Bioaccumulative
vBT	Very High Concern for Bioaccumulation and Toxicity
vP	Very Persistent
vPT Toxicity	Very High Concern for Persistence and Toxicity
vPvB	Very Persistent, Very Bioaccumulative
WEEE	Waste from Electronics and Electrical Products
WEEE Directive	EU Waste Electrical and Electronic Directive
WOE	Weight of Evidence

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
JOEL TICKNER

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.

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- 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 policies⁶ 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 Initiative⁸ 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 socioeconomic 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 implications¹⁴ — 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

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MODULE 1

Policy Options for Generating Information for Sound Chemicals Management

■ RICHARD A.
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How can states best develop chemical hazard and exposure data and what factors must be considered in developing and using such information?

Information is critical to sound decision-making, and chemicals policies are no exception. Indeed, a core function of a chemicals policy should be its ability to facilitate or require the generation of information that can be used to identify and characterize a chemical, understand its manufacturing and use, assess its hazards and exposure potential, and so forth.

In considering the role of information generation in chemicals policies, there are several basic questions:

- What types of decisions are to be informed by the information?
- What types of information may need to be generated?
- What characteristics of the information determine its utility, adequacy, quality, and confidence level?
- What methods can be used to generate the information?
- What options are available to government to facilitate or require information generation?
- How can the reliability of information be enhanced?

This module will explore each of these issues, highlighting important policy considerations and options.

PROBLEM STATEMENT

Current federal policy is plagued with constraints with respect to the generation of chemical information and providing access to it. Some of the major constraints are described below.¹

Dearth of Data on Industrial Chemical Hazards

Current U.S. policy toward industrial chemicals² creates a number of significant barriers to the development of better information about chemical hazards. First, by allowing the tens of thousands of unassessed chemicals already in commerce to remain in use without condition, it effectively rewards ignorance rather than knowledge. Only if government somehow obtains or develops information sufficient to demonstrate a chemical “presents or will present an unreasonable risk” does it have the authority to prohibit or restrict its production or use. In such a climate, companies have little incentive to test their chemicals for potential hazards since doing so would only increase the likelihood that evidence of harm would be found.³

EPA is not required to assess industrial chemicals already in commerce and hence is unlikely on its own to encounter evidence of potential risk. Indeed, EPA has assessed fewer than two percent of the chemicals that were in commerce when the Toxic Substances Control Act (TSCA) was enacted;⁴ these assessments were spurred mostly by EPA’s receipt of information from industry, other governments, or the public indicating potential risk.

EPA does review new chemicals on the basis of the limited information required to be submitted by companies in the Premanufacture Notifications (PMNs) they must file before they can commence production. However — unlike virtually all other developed countries — TSCA does not require (or allow EPA to require) a minimum base set of data on a chemical’s environmental fate and behavior, toxicity or ecotoxicity. Although EPA encourages such data to be included in the PMN, the great majority of PMNs do not.⁵ This lack of data reflects in part the fact that notification takes place at a relatively early point in the course of developing, manufacturing, and marketing a new chemical, when it may not be realistic to expect a company to have conducted much testing. Government intervention at this stage has the advantage of flagging potential concerns before manufacturing has commenced and before significant financial investment has been made by the producer. It also has the potential to allow redesign of the manufacturing process or the chemical itself to eliminate or reduce the concern in advance of commercialization.⁶ However, the lack of data on a chemical’s hazards and other properties, and the more speculative nature of information on its potential uses, releases, and exposures can severely limit the robustness of any risk evaluation conducted at this stage.⁷ This limitation is exacerbated further by the fact that typically there is only one opportunity for EPA review of a new chemical.

Second, government’s ability to compel the generation of hazard information is also constrained: to require a company to test a chemical, government must already have substantial information about it — enough to demonstrate that it “may present an unreasonable risk” or that it is produced in large quantities and results in significant environmental releases or human exposures — a classic Catch-22: **EPA must already have substantial evidence of potential risk or high exposure to direct a company to develop information needed to determine whether there is actual risk.**⁸ To compel testing, EPA must promulgate a regulation, which typically takes many years and substantial agency resources. These burdens are sufficiently high that, in the 30 years since TSCA was enacted, EPA has required testing for fewer than 200 chemicals.⁹

The magnitude of the hazard data gap for industrial chemicals was illuminated in a series of studies conducted in the 1980s and 1990s that documented the dearth of publicly available hazard data even for those chemicals produced and used in the largest quantities. These efforts culminated in a 1998 EPA report that found that 43 percent of the roughly 3,000 chemicals produced in annual quantities of one million pounds or more (so-called high production volume, or HPV, chemicals) had no publicly available screening-level hazard data, and only seven percent had a complete screening-level base set when measured against an internationally agreed minimum data set.¹⁰

These circumstances — large data gaps and limited regulatory authority — have led EPA to rely on voluntary efforts to obtain more information on existing chemicals. The most notable of them is the U.S. High Production Volume (HPV) Chemicals Challenge Program,¹¹ which enlists producers of HPV chemicals to voluntarily develop and make publicly available a “base set” of screening-level hazard information¹² on their chemicals. The HPV Challenge is the only systematic effort by EPA to call for basic hazard data on a relatively large number of existing chemicals. Because it is voluntary, it also sidesteps the “unreasonable risk” and other findings EPA must make to compel data development and submission. However, for the same reason, EPA also has had limited recourse to ensure full participation by manufacturers or the timely submission and high quality of hazard data sets developed for HPV chemicals.¹³

The data gaps and limited authorities just described for industrial chemicals are in marked contrast to the situation for other classes of chemicals, most notably pharmaceuticals and pesticides. For these chemicals — regulated under other statutes — extensive data are required to be generated by their producers and government review and approval are required as conditions for entering or remaining on the market. For example, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), pesticides must be registered with EPA and are subject to extensive testing and government approval processes. As stated by EPA: “Before registering a new pesticide or *new use* for a registered pesticide, EPA must first ensure that the pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment. To make such determinations, EPA requires more than 100 different scientific studies and tests from applicants. Where pesticides may be used on food or feed crops, EPA also sets tolerances (maximum pesticide residue levels) for the amount of the pesticide that can legally remain in or on foods.”¹⁴ Amendments to FIFRA adopted in 1998 also required pesticides already in use to be re-registered and re-assessed for safety.¹⁵

Limitations to Data on Chemical Uses and Exposures

While the federal government does have a number of programs to collect information related to chemical uses, releases, and exposures, each has a number of significant limitations that preclude such programs from providing a comprehensive set of information to inform policy and regulation. This section describes several examples of current programs along with their limitations.

Reporting of chemical use information: For chemicals already in commerce, EPA requires reporting of only limited information on how chemicals are used and the extent to which environmental

releases or exposures to workers, consumers, or the environment may occur, and it does so infrequently. Under TSCA, such reporting can be required only of chemical manufacturers (and in some cases, processors), but not of companies that use chemicals, whether directly or as ingredients in products.

Routine but limited reporting of use and exposure information by manufacturers has just been initiated under EPA's Inventory Update Rule (IUR).¹⁶ Beginning in the 2006 reporting cycle, "known or reasonably ascertainable" information is required of all manufacturers of non-exempt¹⁷ chemicals in amounts of 25,000 pounds or more per year per site pertaining to:

- The number of workers reasonably likely to be exposed to the chemical substance at the site;
- Physical form(s) of the chemical substance as it leaves the submitter's possession, along with the associated percent of total production volume; and
- The maximum concentration of the chemical substance as it leaves the submitter's possession.

For chemicals manufactured in amounts of 300,000 pounds or more per year per site,¹⁸ additional information must be reported, to the extent it is "readily obtainable," on: the number of downstream processing and use sites, numbers of workers reasonably likely to be exposed to the chemical substance across all such sites, types of commercial and consumer uses, amounts in each use category, and maximum concentrations in commercial and consumer products.

Fewer than 10,000 chemicals are now covered by any reporting requirements and only a few thousand of them will be subject to the more extensive reporting that extends to downstream processing and use information. Reporting is required only once every five years and then only for a single reporting year. EPA's experience with past IUR reporting of production data (which used to occur every four years) shows that there is enormous fluctuation from one reporting cycle to the next that must reflect underlying changes in chemical use patterns.¹⁹ These data demonstrate that infrequent reporting yields a highly inaccurate picture of actual manufacturing levels over time, and this inaccuracy is likely to extend to the use and exposure information EPA is now beginning to collect.

Under TSCA Section 8(a), EPA can use case-by-case rulemaking to require manufacturers and processors of specified chemicals to report basic manufacture and use information.²⁰ Each such request requires a separate rule and provides for only one-time reporting, although a single rule can cover multiple chemicals. EPA has standardized this type of regulation in the form of a Preliminary Assessment Information Reporting (PAIR) Rule, approximately 33 of which have been issued for about 1,200 chemicals.²¹

For new chemicals, Premanufacture Notifications (PMNs) that are required to be filed at least 90 days before commencing manufacture must include basic information on anticipated use, production volume, exposure and release — to the extent it is known or reasonably foreseeable by the submitter at the premanufacture stage. TSCA does not provide for any updating of that information once manufacture actually begins, outside of any IUR reporting to which the chemical may become subject.

Environmental release information: Generation or calculation of data on direct environmental releases and exposures takes place under a few programs at the federal level. Under the USEPA's Toxics Release Inventory (TRI) Program, certain types of facilities are required to annually report measured or calculated quantities of each of about 650 designated chemicals that they release to air or water or manage in the form of wastes (including through disposal, treatment, recycling, or burning for energy recovery, either on- or off-site).²² These facility-specific data are then made public. As with IUR reporting, however, the reporting thresholds have recently been raised; for most TRI chemicals, full reports detailing amounts and means of release or waste management, previously required for facilities releasing or handling more than 500 pounds annually, are now required only if more than 5,000 pounds are released or managed, as long as 2,000 pounds or less is released. Below the thresholds, only a certification is required, devoid of quantities or release/management information.²³

Environmental monitoring: The federal government also conducts limited monitoring of chemicals in environmental media. For example, in recent years the U.S. Geological Survey's (USGS) Toxic Substances Hydrology Program²⁴ has pioneered the analysis of selected U.S. surface and ground waters for the presence of various types of chemicals, including industrial and agricultural chemicals, but also so-called "emerging contaminants" such as human pharmaceuticals (for example, the antibiotic sulfamethoxazole), and ingredients used in personal care and other formulated consumer products like detergents (for example, nonylphenol, a breakdown product of a common class of surfactants). The latter are chemicals for which monitoring has typically not been required and were long assumed to be removed by wastewater treatment and hence not enter the environment. Yet USGS data show that dozens of such chemicals can routinely be detected in such watersheds, and are found in highest concentrations just downstream of wastewater treatment plants but are also present in more pristine waters.²⁵ According to the USGS, such chemicals "are commonly present in streams and, to a lesser extent, aquifers, particularly at sites that are immediately downstream or down gradient of contaminant sources. Detection of multiple [chemicals] was common, with as many as 38 being found in a single water sample. These results indicate that synergistic or additive effects from mixtures will need to be evaluated... Some of the most frequently detected compounds included cholesterol (plant and animal steroid), DEET (insect repellent), caffeine (stimulant), triclosan (antimicrobial disinfectant), and tri(2-chloroethyl) phosphate (fire retardant)."²⁶ As USGS points out, however, these data are often hard to interpret as water quality standards do not exist for most such chemicals and the nature and extent of their biological significance for both aquatic organisms and humans (through food chain and drinking water exposures) has yet to be determined. Answering these kinds of questions will require research and funding well beyond that made available to USGS.

Biomonitoring: Since 1999, through the Centers for Disease Control's National Health and Nutrition Examination Survey (NHANES), the federal government has measured the levels of a limited number of chemicals and their metabolites in samples of human blood and urine every two years. The latest survey was published in 2005 and tested samples collected in 2001 and 2002 for 148 chemicals. While many of the chemicals included are either "historical" (for example, banned pesticides, PCBs) or unintentionally produced substances (for example, polycyclic aromatic

hydrocarbons, dioxins), human biomonitoring for substances still in commerce (for example, phthalate esters, cadmium, mercury, a variety of pesticides) has increased in the more recent survey. Such biomonitoring represents the most direct evidence for, and a means of measuring, human exposure, but to date has focused on chemicals already known to be hazardous and on chemicals that tend to bioaccumulate, which are only a subset of chemicals of potential health concern. Government has yet to conduct broader, more exploratory biomonitoring — aimed at identifying the full range of xenobiotics to which humans are exposed, as one means of identifying chemicals that are priorities for further scrutiny with respect to both hazard and exposure. In addition, the extent of sampling conducted to date is too limited to provide the degree of geospatial “resolution” that is needed to begin to elucidate exposure routes for chemicals found in human tissues.

WHY INFORMATION ON CHEMICAL HAZARD, USE, AND EXPOSURE IS IMPORTANT

Having at least basic, reliable, and current information on how chemicals are produced and used as well as their potential hazards and exposures can help to identify and prioritize chemicals of concern for further assessment and risk reduction and management efforts. Such information is also critical in tracking the effectiveness of such measures in actually reducing releases and exposures. Equally important, generating a broad base of information about most if not all chemicals in commerce aids in identifying not only chemicals of concern, but also chemicals that pose little or no risk and hence may serve as potential alternatives or replacements for the riskier ones.

It is important to clearly and explicitly characterize the extent of information available on chemicals. In this regard, attention should be drawn to **data gaps** as well as available data on chemicals. Knowing what information is **not** available about a chemical can be important to assessing the level of confidence that can or should be placed in decisions concerning that chemical. And prominently identifying missing data can provide incentives to develop more and better data.

Finally, independent of the extent to which government itself acts on chemical information to identify and reduce or manage risks, the generation of such information — coupled with providing broad access to it — can empower a host of other actors to make better decisions about the chemicals they produce, use, sell, or purchase. Access to such information may well drive market demands for more information and migration away from chemicals known or suspected of being risky, even without direct government intervention.

TYPES OF DECISIONS FOR WHICH INFORMATION IS NEEDED

Decisions clearly need to be informed by information, but how much is needed? Which types and how much information is needed, and how comprehensive, detailed, and reliable it needs to be, depend on what type of decision is being made. Seeking to match and align the decision being made with the extent of information needed can be important, for several reasons. Generating

and managing information require resources (time, money), so requiring more information than is needed or can be managed can be inefficient or even counterproductive. Some types of decisions can be made with less complete or certain information, and demands for more information can result in or even be intentionally used to engender “paralysis by analysis.”

A range of types of decisions requiring chemical information can be envisioned, for example:

- Review of chemicals prior or subsequent to their manufacture or use in particular applications;
- Initial screening or prioritization of chemicals for further scrutiny or action;
- Determination of additional information needs;
- Assessment of a chemical’s hazard, exposure, or risk;
- Chemical design and product development;
- Selecting among alternatives for a given use or function;
- Determination of needed controls by government or industry;
- Development of regulations; and
- Development of purchasing policies or criteria.

While there is no magic formula to determine information needs for a given decision, some general principles can be articulated. First, some decisions require less or less certain information than others. Screening decisions—where a relatively high capture rate of “false positives” can be tolerated in exchange for minimizing the exclusion of “false negatives”—can often place lower demands on both quantity and quality of information, since initial capture decisions will typically be revisited and potentially revised using more and better information.

Second, some decisions require only certain types of information. A decision to identify a chemical as sufficiently hazardous as to require the development of better exposure information — for example, to list a chemical on the TRI and require reporting of information on environmental releases — does require good hazard information but should not hinge on significant evidence of exposure (and hence risk), since the very purpose of the decision is to develop such information. Conversely, evidence of exposure (for example, through biomonitoring) should suffice to justify the initiation of fairly extensive hazard data development.

Third, decisions being made at design or pre-commercial stages of a chemical’s life — such as a company deciding whether to proceed with product development or which among several alternative substances to choose, or government deciding whether to allow manufacture to commence — may warrant, or may of necessity only be possible to be informed by, less information than decisions that affect more established chemicals. Thorough testing of early product prototypes may not be practical or desirable, whereas such testing should typically be demanded for a chemical already in or headed toward widespread or high-volume production and use.

In general, decisions that are of a more tentative nature or those made at an early stage in a process (be it in the course of product development or development of a regulation), and hence are likely to be revisited or reconsidered, may tolerate less information, while more definitive and impactful decisions demand more. Of course, mechanisms are needed to ensure that both the development

and reconsideration of better information actually take place as the degree of confidence needed in a decision increases.

Finally, decisions to collect or generate certain types of information may be triggered by what previously collected information reveals: For example, detection of a chemical in a biomonitoring program could lead to a decision to require more extensive testing for hazardous properties, or, conversely, evidence of hazard to humans or environmental persistence could trigger a requirement to conduct biomonitoring for a chemical. Data in some cases may be developed through *tiered* approaches, where indications of adverse effects in a set of relatively simple or inexpensive tests (often called screening-level tests) would trigger more extensive testing. While such approaches are widely used, there is considerable concern about sensitivity, that is, the ability of some screening tests (for example, *in vitro* or very short-term *in vivo* tests) to detect the longer-term or chronic effects that really matter.

TYPES OF INFORMATION THAT MAY BE NEEDED

Broadly speaking, several major types of information may be needed to inform sound decisions concerning safe management of chemicals. They include:

- Information on a chemical's inherent characteristics:
 - Identity, trade name(s), molecular structure, composition, physical-chemical properties, physical form, and so forth.
 - Environmental fate and behavior in various environmental media, including its partitioning and transport among various environmental compartments and its potential to accumulate in them; its persistence and susceptibility to degradation (as well as the identity and characterization of breakdown products); and so forth.
 - Biological fate and behavior, including its proclivity for being taken up into or entering living organisms; its movement and distribution within them; its biopersistence and potential to accumulate or be metabolized, degraded, or otherwise transformed; and so forth.
 - Toxicity to living organisms.
- Information on production, handling, use, and lifecycle management:
 - Where, in what quantities and forms, and how the chemical is — and is recommended to be safely — produced, processed, handled, stored, and transported.
 - Its functional characteristics, and in what form(s), for what purpose and how the chemical is used, and what alternatives are available.
 - Its fate after use.
- Information concerning potential and actual releases and exposures:
 - How and to what extent the chemical is released and people (workers, consumers, general public) or the environment are or could be exposed to it.
 - The extent of its presence in the environment and organisms, including humans.

IMPORTANT INFORMATION CHARACTERISTICS

Many other characteristics of the information will determine if, when, and where it is needed, useful, and appropriate to be used for a given decision. To be of use, the information must be sufficiently reliable (for example, current, accurate, viewed as credible) and timely (that is, collected or generated and made available at the right time to inform a decision).

The quality of and degree of confidence that can be placed in chemical information are important considerations, and need to be characterized and communicated as explicitly as possible. It is also critical to ensure that any resulting limitations with regard to appropriate and inappropriate uses of the information are understood and communicated. Measures and dimensions of quality can include:

- Sufficiency of scope and representativeness (for example, the fraction of total production or use included; spatial and temporal extent, number of and frequency of samples taken in monitoring; number of species or strains subjected to toxicity testing);
- Extent of adherence to established and standardized methods, including good laboratory practice;
- Extent of validation of methods, models, and results;
- Extent of documentation provided, including extent of access to underlying raw data;
- Extent to which results have been replicated or are independently verified or verifiable;
- Currency;
- Extent to which data are empirically measured, estimated, modeled, derived through expert judgment, based on assumptions;
- Characterization and clarity in communication of confidence level or other measures of reliability; and
- Publication, peer review.

Appendix A provides a fuller discussion of steps needed to enhance the quality and reliability of chemical information, especially that generated by industry.

As noted earlier, the extent to which data are **complete** — or alternatively, the extent of data gaps — can also be an important measure of data quality. Being able to identify such gaps requires, of course, an accepted benchmark for what constitutes sufficient or “complete” data — which can in turn depend on the purpose and use of the data. Minimum data sets have been developed and used in a number of regulatory and voluntary programs (for example, data required for new chemical notifications in Canada and the Organization for Economic Co-operation and Development’s (OECD) Screening Information Data Set (SIDS) used in the HPV Challenge). Perhaps equally needed but as yet not well developed would be an articulation of the desired amount of information that should be available for all chemicals, or for chemicals used in particular ways (for example, present in consumer products). Such data sets could serve effectively as both yardsticks and goals for measuring progress in closing the gap between what we know and what we should know about the chemicals we make and use.

METHODS AVAILABLE TO GENERATE INFORMATION

Information on hazard and exposure can be developed by a variety of means, which may well differ in their associated uncertainty or confidence level. Information can be derived:

- Empirically through measurement or testing, for example:
 - Through epidemiological studies or biomonitoring;
 - Using *in vivo* or *in vitro* toxicity test methods; or
 - Sampling and analysis to measure airborne concentrations in a workplace setting or releases to wastewater.
- By estimation through models or interpolation/extrapolation, for example:
 - Using a quantitative structure-activity relationship (QSAR) model;²⁷
 - Using “read across” from structurally related chemicals;²⁸ or
 - Using an exposure model to estimate, for example, the concentration of a chemical remaining in ambient air following a release or the fraction of a chemical not degraded in a wastewater treatment plant.²⁹
- Exercising expert and experience-based judgment, for example:
 - By applying weight-of-evidence (WOE) approaches to resolve conflicting information or combine pieces of information, none of which alone would be deemed sufficiently reliable but which together support a conclusion; or
 - By using assumptions considered reasonable in the absence of hard information.³⁰

Data generated using these different methods possess inherent differences that in turn affect their expected reliability and hence delimit their appropriate use. This factor reinforces the need to align the degree of confidence needed for the decision being made to the degree of confidence that can be expected from the methods being used to generate information.

The table following displays the rough correlation between the range of methods available; their relative reliability, cost, and speed of execution; and their suitability for different types of decisions. One key assumption is made: that data are of good quality.

The next section describes characteristics and experience with the use of the various available methods for assessing hazard, while the section following it does so for exposure-relevant information.

Testing for Hazard and Alternative Methods

Methods in each of the above categories typically have been used or are allowed to be used to meet data requirements in voluntary programs (for example, U.S. High Production Volume (HPV) Chemical Challenge,³¹ OECD SIDS Program³²) and many regulatory programs (for instance, the European Union’s REACH Regulation,³³ Canada’s New Substances Notification Regulations³⁴).

Methods to assess:	Empirical measurement methods			Estimation/prediction
Hazard	epidemiological studies	<i>in vivo</i> testing	<i>in vitro</i> testing	QSAR/read-across
Exposure	biomonitoring	workplace monitoring		exposure modeling
		environmental media monitoring		use categories
		measuring releases		
COMPARATIVE				
Reliability	VH	H	M	L
Cost	VH	H	M	L
Speed of development	L	M	H	VH
APPLICABILITY TO				
Screening/initial review	L	M	H	VH
Final decisions	VH	H	M	L

L = low; M = medium; H = high; VH = very high

Hazard data derived from these methods also have been used by government authorities to screen or prioritize chemicals for further scrutiny or management. For example:

- As noted earlier, unlike most other developed countries, U.S. law does not require chemical manufacturers to provide a “base set” of measured hazard data when notifying authorities of their intent to make a new chemical, and hence the great majority of new chemical notifications submitted in the U.S. lack such data. In addition, EPA is given only 90 days to decide whether a chemical needs any restrictions placed on its manufacture or use; if it fails to act, manufacture can commence. For these reasons, EPA’s New Chemicals Program has developed and made extensive use of quantitative structure–activity relationship (QSARs) and category read-across approaches to predict the hazards of chemicals it reviews that lack actual test data.³⁵
- Under Canada’s recently completed Domestic Substances List (DSL) Categorization process, Health Canada established a “data hierarchy” which clearly recognizes that the confidence level associated with information from different sources and from the different methods described above varies. Health Canada therefore considered them in the order of their associated confidence level, as described below:

For each endpoint, the substance-specific sources of information are also considered hierarchically, with those in which there is greatest confidence being addressed initially. Acceptable assessments of international or national agencies and secondary reviews are consulted initially, followed by original study accounts. If relevant data from these

sources are not identified or are insufficient, predictions of QSAR models, information on chemical substructures of concern and analogues or surrogates are considered subsequently.³⁶

- The State of Washington recently commissioned an assessment of alternatives to the flame retardant decabromodiphenyl ether (deca-BDE) that used QSAR model estimates to supplement the test data available to characterize the relative hazards of deca-BDE and the alternatives. The models employed were the same as those used by EPA's New Chemicals Program.³⁷

Interest in promoting alternatives to traditional chemical testing is motivated by a desire to gain efficiencies in assessing new chemicals prior to market introduction as well as in addressing the huge backlog of un- or under-assessed chemicals already on the market; reduce the costs associated with traditional testing; and reduce unnecessary use of laboratory animals. They are all worthy objectives. At the same time, it is critical that an appropriate balance be struck with other equally important objectives: assuring full protection of human health and the environment; basing decisions on scientifically sound and defensible information; ensuring that all assessment information used to make such decisions is independently verifiable and reproducible; and maximizing transparency in communicating the basis for decisions to stakeholders and the general public.

Transparency: With any information, but especially that generated by alternative methods, transparency is key in both use and communication of conclusions or decisions based on the information. The nature, source, and means of derivation of each data value needs to accompany it in any subsequent presentation or communication of the data, and should be an integral part of the justification provided for any conclusions or decisions based on such data. An assessment of the degree of confidence in or reliability of the data is another prerequisite to transparency, and any resulting uncertainty should be captured and communicated through a clear articulation of appropriate qualifications or limitations that apply to conclusions or decisions based on such information.

Continuing need for generation of experimental data: Another essential point is that development and improvement of many alternative methods is highly dependent on having a robust and expanding underlying dataset of values derived from *in vivo* testing. Such data are necessary both for the development and refinement of the algorithms that underpin mathematical predictive models (for example, QSARs), and to allow correlations to be established between *in vivo* results and those of other systems (such as *in vitro* testing). At least in the near term, these alternatives will only be as good as the *in vivo* data that underpin them; without an ongoing commitment to enhance databases derived from *in vivo* testing, the applicability and reliability of such alternative methods will not progress to the point where they can fully replace *in vivo* test systems.

Hence, use of alternative methods to direct *in vivo* testing has its place, but they must be used appropriately and with caution, and only where all parties understand how and when to use the methods, how to interpret and apply the results, and what the limitations of the methods are.

Important considerations regarding appropriate uses, advantages, and limitations for some of these methods are discussed in Appendix B.

Appendix A provides a fuller discussion of steps needed to enhance the quality and reliability of chemical information generated using alternatives to direct in vivo testing.

Generation and Use of Exposure Information

Three types of uses of information about chemical exposures are prevalent in existing practice. First, exposure information is used directly, in combination with hazard information, to assess the risks posed by a chemical, typically under the rubric of risk assessment methodologies. Second, exposure information is used to identify chemicals of concern or to prioritize among multiple chemicals, so that chemicals to which there is significant exposure can be targeted for further assessment or control. For example, biomonitoring provides a direct means to identify which chemicals humans or non-human organisms are exposed to. (Typically, however, chemicals are selected for biomonitoring based on some degree of pre-existing evidence of hazard, that is, chemicals are chosen for which there is already evidence of toxicity, persistence, or bioaccumulation potential.)

Third, and more controversial, exposure information can be used to “moderate” the extent of hazard testing required to be conducted or, for a chemical already identified to be hazardous, the priority given to further assessment or risk management. An example of the former is REACH, under which “substance-tailored exposure-driven testing” is available for all of the testing elements required for chemicals in the two highest tonnage tiers, and two elements required for chemicals in the third highest tonnage tier; the waiver is available to any registrant that can demonstrate that exposure to a chemical is low.³⁸ An example of the latter is the OECD SIDS Program, under which even a hazardous chemical can be deemed a “low priority for further work,” based on consideration of minimal information that suggests exposure is “anticipated to be low.”³⁹

While both hazard and exposure are clearly relevant in determining chemical risks, there are critical differences between our ability to assess hazard and exposure that have implications for the development and application of chemical exposure assessment policies. And real-world experience in chemical assessment programs that have attempted to rely on exposure information to prioritize chemicals also offers lessons for exposure assessment. Serious and intrinsic limitations apply to the generation and use of exposure information, as described below.

Key differences between assessing hazard and exposure: Hazard is largely inherent to a substance, while exposure changes with place, use, and time. This means that hazard (and hazard characterization or assessment) is relevant whatever the setting or use, while exposure is highly site/use-specific. Any exposure assessment is necessarily a “snapshot” of current exposure; the next new use or activity alters the picture. Exposure assessment must therefore be ongoing: scope, frequency of measurement must characterize *variation* in as well as *magnitude* of exposure.

Mechanisms for generating and evaluating hazard data are far more advanced and accepted than for exposure data. Extensive international-consensus standards exist for generating hazard data; they also address quality/reliability, interpretation, and reproducibility/verifiability. In contrast, standardized and routine collection of exposure data is rare and infrequent, and public access to such data is even rarer.

For the first time, beginning in 2006, U.S. EPA will begin to require the reporting of basic information relevant to understanding uses of and exposure to chemicals,⁴⁰ although it will be limited to several thousand high-volume chemicals, and will be collected only once every five years — despite enormous documented variability in these chemicals' production volumes⁴¹ that presumably also reflect changes in their underlying use patterns.

Differential access to both exposure data and the means to generate them can severely limit the “reproducibility” of such data. Most exposure data and the means to generate them reside virtually exclusively with industry. Industry's interest in claiming low exposure must be acknowledged, and means that having the ability to independently verify such information is essential. It must also be acknowledged that direct access to exposure “settings” is limited even for government officials. In addition, as noted earlier, confidential business information (CBI) restrictions limit public access to exposure-relevant data; in contrast, hazard data are typically ineligible for CBI protection. Finally, supply-chain impediments to sharing exposure-relevant information abound, where for competitive reasons both suppliers and their customers have only limited access to information in the possession of the other party.

Implications for policy: How should policies and practices address these current realities?

There is a critical need to develop international consensus guidelines governing the generation and use of exposure information, addressing:

- Scope, completeness, and quality;
- Means of collection, analysis, QA/QC, verification, validation and reporting/ presentation transparency; and
- Representativeness (accounting for both spatial and temporal variability).

Equally important is to ensure the capacity exists and is used to provide adequate expert review of any reliance on exposure information, to ensure that resulting conclusions or decisions:

- Explicitly assess the information's scope, completeness and quality;
- Sufficiently acknowledge limitations and the degree of uncertainty; and
- Fully qualify conclusions.

Chemical assessment policies must acknowledge and directly address the variable nature of exposure. This means that exposure must be periodically reassessed to account for changes over time in production and use patterns. A corollary need is that requirements for the prompt reporting of such changes needs to be in place. To the extent that modeled as opposed to measured data are relied on to provide exposure estimates, policies need to outline procedures to be employed

to validate the models, provide public access to the models and their underlying data sets. Just as for measured data, policies also need to ensure that models effectively account for variation in exposure over time.

With respect to the differential access to exposure-related information, government officials need to be provided with authority and be able to demonstrate their ability to independently verify exposure data submitted by industry. Industry should itself commit to mechanisms such as third-party review and public release of all such data. Steps to de-bottleneck supply-chain flows of exposure-relevant information need to be instituted, by both industry and government. Finally, the allowed scope of CBI claims for such information should be as limited as possible.

Reliance even on reliable and complete exposure information does not preclude the need to develop a hazard characterization for a chemical, which has value independent of exposure and will virtually inevitably be needed as the exposure situation changes.

GOVERNMENT'S OPTIONS FOR GENERATING INFORMATION

Sometimes chemical information already exists and can simply be collected and compiled, while in other cases it must be generated *de novo*. Some chemical information may be largely in the possession of those companies that produce and use the chemical, while some may be independently accessible or able to be developed. Finally, such information may be published or otherwise publicly available, or it may be unpublished or inaccessible (for example, confidential business information).

Government has several basic options when it comes to facilitating the reporting or generation of chemical information. It can:

- Itself collect or generate the information;
- Require commercial producers or users of chemicals to report existing or generate new information;
- Request that information be provided voluntarily or provide incentives for companies to do so; or
- Help to develop and shape a market in which the collection or generation of the information has economic value.

Each of these options is discussed below, along with advantages and disadvantages of each. The table below shows a rough side-by-side comparison of these options, based on criteria reflecting these advantages and disadvantages.

	Gov't generation of information	Gov't mandate to industry	Gov't voluntary programs	Gov't provision of information access
Burden on, resources req'd of gov't	VH	M	L	L
Burden on, resources req'd of industry	L	VH	H	?
Reliability of, trust in information	VH	VL	VL	?
Extent of public access	H	H	M	H?
"Green chemistry" capacity building in industry	L	H	M	?
Incentives to disclose information	VH	?	?	?
Ability to ensure desired outcome	VH	VH	M	L
Empowering of others to act	M	M	M	H

L = low; M = medium; H = high; VH = very high; ? = uncertain

OPTIONS

1. Government can itself collect or generate the information.

Government can directly conduct testing of chemicals; measure or monitor for them in workplaces, environmental media or humans or other organisms; or apply models to develop estimates or predictions in the absence of data. This activity can be undertaken through research agencies (for example, NIEHS, NIOSH) or government laboratories (for example, EPA labs), or in some cases by regulatory agencies. Examples of government-developed chemical information include toxicological testing conducted by the National Toxicology Program, biomonitoring of human blood and urine conducted by the Centers for Disease Control, and workplace inspections and air sampling conducted by the Occupational Safety and Health Administration.

Advantages of direct government generation of information include the following:

- The information will be associated with a relatively high degree of public trust.
- Government has direct control over the methods used, the documentation provided, and other factors important to developing reliable data in a transparent and accountable manner.
- Government, and potentially the public, has full access to the results and underlying data.

Among the disadvantages or limitations are the following:

- Government bears the cost of generating the information.
- For government to routinely generate data on large number of chemicals could well exceed available financial and human resources, including potentially laboratory capacity.
- For new chemicals just being developed or yet to be commercialized, it is more difficult to see how government could intervene.

- Government conducting all testing could effectively undermine incentives for companies to maintain and enhance their expertise and capacity to consider risk in chemical design, that is, green chemistry, and pollution prevention approaches.

2. Government can require commercial producers or users of chemicals to report existing or generate new information.

Government imposition of requirements for industry to report existing information or generate new information is probably the most common approach used by government to develop chemical information. This approach is used across all major types of chemicals, including pesticides, pharmaceuticals, and industrial chemicals. Testing requirements are most commonly imposed at the time of a chemical's first introduction. Examples of this approach include the registration of pesticides under the U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); premanufacturing notification requirements for new chemicals (where EPA can but relatively infrequently imposes testing requirements on a case-by-case basis⁴²), and reporting and test rules, and inventory update reporting requirements for existing chemicals, all under TSCA; and the reporting, testing, assessment, and risk management requirements under the Registration provisions of the European Union's REACH Regulation.

Under TSCA, information reporting and generation requirements can typically only be imposed through full notice-and-comment rulemaking. Testing rules — in contrast to rules requiring the reporting of already existing information — require that government makes certain findings that a chemical poses significant potential risk or high exposure. The development of test rules consumes significant time and resources, and hence is used only infrequently.⁴³ Where EPA determines that additional data are needed to assess a new chemical, rather than promulgate a regulation, it typically negotiates with notifiers an agreement to conduct testing, which is known as a Voluntary Testing Action.⁴⁴

Advantages of government compelling industry to report or generate information include the following:

- It embodies a shift in the burden of information development, if not proof of safety, to the producers and users of chemicals and away from government.
- Information can potentially be developed on many more chemicals than government would be able to generate by itself.
- Industry potentially has an incentive to develop and use safer chemicals, in order to avoid having to report information indicating potential hazard or risk and be required to take action to mitigate risk.

Disadvantages and limitations include the following:

- Industry has an incentive to downplay hazards or risks of its chemicals, which has the potential to compromise the reliability of the information it generates.
- Selective reporting is a concern, although requirements exist in most jurisdictions compelling industry to submit any information indicative of significant risk.

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- Under current statutory authorities in the U.S. and Canada, government must generally demonstrate that an existing chemical may pose a significant risk in order to compel any testing.⁴⁵ Under the REACH Regulation in the EU, preset requirements (the extent of which are tied primarily to production volume) to test or submit testing proposals are applicable to existing chemicals;⁴⁶ in order to compel testing beyond these requirements, government is not explicitly required to demonstrate potential risk, but any proposed testing requirement must undergo an extensive consensus review process among all member states, with rights of appeal for the producer.⁴⁷
 - Government resources required to review industry data for quality, accuracy and completeness are still substantial.
 - Public trust is typically much lower in information generated by industry than by government.

3. Government can request that information be provided voluntarily or provide incentives for companies to do so.

Prominent examples of this approach include the U.S. HPV Challenge⁴⁸ and the OECD's SIDS Program. Another example where EPA has encouraged and provided an incentive to industry to develop and submit information is the Sustainable Futures Initiative. Companies participating in the initiative receive training and agree to employ the same suite of tools EPA uses to assess new chemicals. In exchange, participants can qualify for expedited review of their new chemical submissions, receive public recognition, and for small businesses, gain access to technical assistance from EPA. Through the initiative, several companies have screened their new chemicals using EPA's methodologies, and screened their existing chemical inventories to identify, and in some cases eliminate or reduce their use of, PBTs.⁴⁹

Advantages, in addition to those listed above for regulatory approaches, of voluntary efforts through which industry reports or generates information include the following:

- They bypass statutory findings regarding risk that must be made in some jurisdictions to compel testing.
- They can often be implemented more quickly than can regulations.
- They are less likely to be contested by industry than regulations.

Disadvantages and limitations, in addition to those listed above for regulatory approaches, include the following:

- Government has little recourse if data quality is poor, data are incomplete, deadlines are not met, or agreed procedures are not followed, since there is no legally binding obligation imposed on companies.
- The extent of participation is difficult to predict.
- The ultimate incentive for companies to participate is likely the extent to which government can compel testing if the extent of voluntary participation is deemed insufficient; hence, the very limitations and constraints government faces in seeking to develop regulations may also significantly influence the extent and quality of voluntary participation.

4. Government can help to develop and shape a market in which the collection or generation of the information has economic value.

Government's provision of broad public access to chemical information it acquires by whatever means can itself significantly affect market dynamics and other economic dimensions of decision-making about chemicals; in this context, the "public" includes end consumers; governmental and non-governmental institutions (for example, hospitals), companies that purchase chemical products; and companies that make or sell such products. Indeed, a field of specialization within economics known as information economics has demonstrated that access to information is a critical need if markets are to operate properly, and, conversely, that the lack of robust information can adversely affect market economies.⁵⁰

One of REACH's main strengths is the extent to which the government intends to make public a large amount of the information it receives (as well as the decisions it makes and the basis for them), including the identification of substances of very high concern that are to be subject to authorization and information about potential substitutes. Access to such information may well drive market demands for more information and migration away from chemicals known or suspected of being risky, even without direct government intervention.⁵¹

The registration requirements for pesticides under FIFRA and the EU's REACH Regulation establish that companies must demonstrate that they have rights to the information they submit to meet information requirements. If they did not themselves generate the information, they are generally required to compensate the owner of the information to gain the right to use it—thereby imparting monetary value to the information.

California's Proposition 65 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—unless the amount of the chemical is below an agreed-upon *de minimus* level. In addition to shifting the burden of proof of safety to companies, Proposition 65 arguably economically rewards companies that generate information about a chemical that allows a no-effect level to be set, because they can avoid negative labeling.

Government procurement policies toward products that contain or are made from chemicals can influence the value assigned to chemical information. As large purchasers of products and services, governments represent a significant increment of market demand. Development and communication of clear criteria that will govern governments' purchase of products and services involving chemicals can help drive markets toward production and use of safer and better characterized chemicals.⁵²

Advantages of such approaches include the following:

- They work through and hence are more likely to be aligned with rather than work against market incentives and dynamics.

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- They do not require direct government intervention to control or restrict use of certain chemicals.
 - They potentially empower a much broader array of actors in making informed decisions about chemicals.

Among their limitations:

- It is difficult to predict the nature and extent or ensure the effectiveness of and track actions taken by entities outside government to reduce chemical risks.
- If market dynamics are not working satisfactorily, there is no direct means to compel or increase compliance.

RELEVANCE TO STATE-LEVEL POLICY-MAKING

States have a critical role to play in chemicals policy development and implementation, not only in affecting practice within their borders, but also in innovating new policy approaches and driving national policy forward. The information generation options discussed in this module differ, however, in the extent to which they can or should be pursued or implemented at a national versus state government level, as well as the extent to which any individual state has the capacity or authority to actually do so. A few examples of criteria or considerations that could be used to distinguish among the options with respect to state-national differences are provided here, but are not meant to be prescriptive or limit what options state governments may wish to pursue.

First, a basic distinction can be drawn between information generation options that require the generation of new information versus requiring the reporting of already existing information. Developing and conducting a testing program, especially for large numbers of chemicals, is likely beyond the capacity of most states and is arguably most efficiently and effectively done at a national — or even international — level. (More targeted programs focusing on chemicals of particular concern to a state may well be appropriate, however.) On the other hand, obtaining and using existing information — whether test data or information on chemical uses or releases may be more feasible for most states.

Because the hazards of a chemical are among its intrinsic characteristics, such information is universally useful and can be generated and used independent of a specific place and time. In contrast, information about a chemical's use and human or environmental exposure to it is often specific to a geographic region and may change over time. For this reason, such information may be more appropriately developed at the state level. States can and should take steps to understand which chemicals are produced in or imported into their states, as well as how they are transported, stored, processed, and used. Data on chemical releases and exposures within a state (for example, emissions information, concentrations in a state's environmental media or food supply, biomonitoring of state residents and wildlife, including unique or especially susceptible subpopulations) can provide important geospatial information and be essential to setting a state's priorities for action. Of course, the development and maintenance of databases of chemical

information can be expensive and may entail specialized expertise that is not readily available in all states. Coordination among states in developing and sharing such information may prove useful in extending expertise and resources and in avoiding duplication; for example, a group of states might allocate to specific individual states the task of collecting information for specific economic sectors according to their relative importance to the economies or other priorities of the members of the group.

States can and do differ with respect to their policy priorities, both from each other and from national priorities. These priorities may arise from many different sources; they may be of cultural or historic origins, signify economic conditions, or reflect geospatial distinctions, for example, the extent of reliance on groundwater; location relative to pollution sources in surrounding states; features of the natural landscape (for instance, major watersheds); the nature of land uses or extent of urbanization; or the presence of subpopulations dependent on subsistence lifestyles.

Some states have decided to focus on particular classes or uses of chemicals of concern. The State of Washington, for example, has established as a priority the identification and restriction of PBT chemicals, with an initial focus on mercury and brominated flame retardants.⁵³ As one response to the growing contamination of fish — a key state resource — with mercury, the State of Maine has adopted a product focus, prioritizing the identification and elimination of mercury-containing products.⁵⁴ The emphasis on eliminating uses of mercury has extended the state's actions down the supply chain to focus on companies that use mercury in their products, and has led it to join forces with other states both in the region and nationally.

Given these distinctions, it makes sense that states will pursue different approaches and will vary in the extent to which they pursue the development and use of chemical information. At the same time, states should be communicating and coordinating their activities as much as possible, in order to learn from each others' experiences, share information, avoid duplication and exploit synergies and economies of scale.

CONCLUSION

The development of good information about chemicals underpins all other aspects of chemicals policy, including the other modules explored in this project: Information is critical to the evaluation and prioritization of chemicals, to consideration of options for hazardous chemical substitution and use reduction, to ensuring robust chemical information flows bi-directionally in the supply chain, to innovation with respect to green chemistry, and to overall program administration and implementation. The development of more and better information will allow us not only to identify which chemicals pose risks, but also which ones pose little or no risk and could replace riskier ones. Indeed, one potentially enormous, but largely unsung, benefit of adopting a comprehensive approach that seeks to develop risk profiles for most or all chemicals would be the ability to select safer chemicals with confidence.

This module has explored the basic questions of what, how, by whom, for whom, and why chemical information is to be generated. Many options are available and each has its own strengths and weaknesses and appropriate and inappropriate uses. But in general, the module argues for taking a broad approach with respect to both the extent of information that should be developed and the range of actors and the ways by which that information can be used. Better information, coupled with greater access to it, will empower a range of others besides government to act to control chemical risks. This includes companies that purchase and use chemicals in their products, retailers that sell chemical products, businesses and institutions (for example, hospitals, hotel chains) that buy chemical products, as well as workers, consumers, public interest groups, government and academic researchers, and the broader public.

APPENDIX A

Ensuring the credibility of industry-generated data and information developed using alternatives to direct testing

Essentially all policies affecting chemicals — whether the industrial chemicals that are the focus of this report, or drugs, cosmetics ingredients, pesticides, or food additives — require or encourage, and almost exclusively rely on, chemical producers to generate and submit data on their chemicals. As noted above, REACH, as well as existing U.S. and Canadian approaches to assessing industrial chemicals, rely extensively on industry data. While the merits of this approach are subject to considerable debate in some circles, implementing viable alternative approaches has proven elusive. It is critical, therefore, that every effort be made to ensure that industry-generated data used to formulate and support public policy are — and are seen as — credible. This need is even more pronounced when one considers the obvious financial incentives industry has in minimizing testing costs and being able to maintain that its products are safe.

Moreover, cost minimization and efficiency objectives, as well as animal welfare concerns, are driving an increasing reliance by both industry and government on alternatives to direct *in vivo* testing, including use of *in vitro* assays, the use of various estimation and extrapolation methods and weight-of-evidence approaches. As already described, these methods have inherent limitations as well as legitimate uses. Both industry and regulatory agencies have less experience with them, and they often require different types of expertise both to properly use and to critically review. Finally, standardization of methodologies and guidance on their appropriate and inappropriate use are less well-developed than for standard testing methods.

Government needs, therefore, to ensure the integrity and appropriate use of these information sources in formulating and executing chemicals policies. Toward that end, consideration should be given to implementing the types of measures indicated below.

- With respect to industry-generated data or other privately funded research, consider:⁵⁵
 - Establishment of a registry of health and safety related studies, to ensure that results of all initiated studies are reported and made available, along with details of the method utilized in each study. This proposal is quite similar to practice already employed in the arena of pharmaceuticals regulation.
 - Requiring government access to all records of privately-sponsored research used in setting or implementing public policy. Such a requirement already exists for public-funded research.
 - Requiring the disclosure of funding sources and extent of sponsor review/approval, as well as potential financial conflicts of interest, on the part of researchers who are privately

funded and whose research is used in public policy settings. A growing number of scientific journals and organizations require such disclosures.

- Requiring independent peer review or certification of studies submitted for use in public policy contexts, along with transparency safeguards to ensure disclosure of the identity of reviewers and any potential conflicts of interest, as well balanced representation of the scientific community among reviewers.
- With respect to alternatives to direct testing, consider steps to:⁵⁶
 - Avoid over-reliance through the creation of and adherence to clear, scientifically sound guidance on the appropriate and inappropriate uses of each alternative method.
 - Require justification and appropriate documentation for both use of and decisions made based on information derived from alternative methods.
 - Ensure careful independent expert review.
 - Implement safeguards to prevent selective use and reporting, for example, by requiring that all results derived using all methods employed be reported to regulatory officials.
 - Require that any presentation or communication of both the data and conclusions or decisions based on data, derived using such methods clearly indicate the nature, source and specific means used to derive them.
 - Require that an assessment be made of the degree of confidence in or reliability of the data, and that resulting uncertainty be communicated and reflected in appropriate qualifications of any conclusions or decisions based on such information.

APPENDIX B

Alternatives to *In Vivo* Testing for Hazard: Important considerations

***In vitro* tests:** *In vitro* tests comprise a gamut of different assays, ranging from relatively simple protein or receptor binding assays to the complex simulation of heterogeneous tissues outside of living organisms. In comparison to the similarly wide range of *in vivo* tests, *in vitro* tests offer certain advantages: reduced cost, reduced or no sacrifice of animals, generally rapid results, and the ability to perform multiple replications or parallel experiments simultaneously. The primary disadvantage of *in vitro* testing is increased uncertainty in interpreting results, due to difficulties correlating observed effects with *in vivo* effects, and the limited ability to account for metabolism or other complex interactions that can moderate or exacerbate toxicity *in vivo*.

While some *in vitro* tests, such as the Ames test, have long been incorporated into predictive toxicology, there are still large knowledge gaps that must be filled before *in vitro* tests can begin to replace *in vivo* tests in most applications. As those knowledge gaps are filled, however, it is likely that there will be specific applications in which *in vitro* tests can form part of an integrated assessment. One such possibility would be the inclusion of high-throughput binding assays for an array of different endocrine receptors, in order to be able to categorize compounds' or mixtures' ability to stimulate various endocrine pathways. Such studies are common in the published literature,⁵⁷ but these methods are not yet common in regulatory use.

In vitro methods hold great promise for more rapid screening of chemical compounds and environmental samples, but they also present many of the same limitations as the use of QSAR models discussed below. Because *in vitro* findings are several steps removed from whole animal histopathology, they are more easily discounted when they suggest a problem. Indeed, many in industry argue that *in vitro* methods should not be relied upon because they are invariably more "sensitive" than the corresponding *in vivo* studies; even where this is the case, however, that property might well be *desirable* if such tests are used as a first-line screen for chemicals. More generally, whether *in vitro* methods are always more sensitive remains to be seen; there simply are not enough correlative data with *in vivo* studies to know at this point. Given this, just as many in industry are concerned about an over-reliance on positive findings from *in vitro* studies, an over-reliance on negative results from *in vitro* methods, in the absence of documentation of their sensitivity, could also lead to erroneous decisions and inadequate public health protection.

As mechanisms of toxicity continue to be elucidated, the utility of *in vitro* testing may well increase, initially for screening of chemicals but ultimately, perhaps, for use in more definitive assessments. In order for this to occur, an intensive effort to determine and map out the relevant mechanisms for a wide variety of types of toxicity is necessary. In addition, regulatory toxicology agencies

and laboratories will need to run selected *in vitro* assays in parallel with traditional *in vivo* toxicological tests on a range of chemicals so that databases that correlate *in vitro* findings with relevant adverse health outcomes can be populated. Initial attempts to incorporate *in vitro* assays into larger, integrated assessments should focus on limited applications with the greatest knowledge base, such as endocrine or metabolic disruptors. Confidence gained in these limited applications may foster increased investment and confidence in broader development and use of *in vitro* assays. As with all of the methods discussed in this module, such confidence will also be dependent on transparency of methods, materials, and interpretation.

Quantitative Structure-Activity Relationships (QSARs): While development and use of QSARs holds considerable promise to reduce testing needs, at present there are significant limitations to their use. Reliable models are available for only a subset of relevant endpoints, and are in particular lacking for most human health-related endpoints, especially chronic ones.⁵⁸ The question of validation continues to be a contentious one, with no clear agreement on what constitutes sufficient validation. Public or even government access to underlying algorithms and training datasets has yet to be assured for many QSARs, due to the proprietary nature of many models — this despite the fact that such access is key to providing needed transparency and accountability in the application of QSAR approaches, especially in regulatory contexts.

Existing QSARs have limited “domains” of applicability, dictated by the nature of the chemicals in the “training sets” used to develop them. Many common types of chemicals often fall outside such domains, meaning they simply cannot be assessed by the models. Finally, the accuracy and reliability of QSAR-derived estimates vary from one QSAR and endpoint to another, and the estimates they generate often vary considerably from available experimental values.⁵⁹

Having a full understanding of both the proper application and the limitations of QSARs is essential to ensuring their appropriate use. To that end, both OECD and USEPA have developed detailed guidance on the use of QSARs in various settings and applications.⁶⁰ OECD has recently focused appropriate attention on the need for validation of QSARs.⁶¹ Two case studies developed by the OECD *ad hoc* Expert Group on QSARs are useful to consider in this context.⁶²

The first case study, from the USEPA, described its use of QSARs in reviewing new chemicals. As noted earlier, because TSCA does not require manufacturers of new chemicals subject to premanufacture notification under TSCA to submit a minimum data set, EPA relies heavily on such models to evaluate these chemicals. In its case study, EPA argued that whether a QSAR is “valid” depends in part on how and for what purpose it is used; e.g., used as a means to rapidly screen and prioritize many chemicals to identify those in most need of further scrutiny, a higher degree of uncertainty may be accepted than, say, for risk assessment purposes. Where the statutory constraints EPA faces do not exist, however, the larger question remains: whether and when QSAR-generated estimates can reliably replace experimental data and hence serve as a scientifically sound alternative to testing. QSAR estimates generated by or submitted to regulatory agencies for use in such a context-specific manner cannot be assumed to be “valid” universally, and hence

should not simply be adopted for use by other countries that do not face the same constraints and may need or wish to develop a more certain basis for regulating chemicals.

An EU country participant contrasted the EPA's use of QSARs versus that to be allowed under REACH: In the former case, the government develops, applies and interprets QSAR results; under REACH, industry would utilize QSARs, and governments would have to be in a position to be able to judge the validity of the results. This difference, it was argued, suggests a greater need for rigorously validating QSARs in advance, at least for this type of use.

The second case study, provided by Denmark, compared experimental data and QSAR estimates for specific. Only five endpoints were able to be compared: biodegradability; acute toxicity to fish, aquatic invertebrates and algae; and mutagenicity. These are the endpoints for which the "best" QSARs exist – those that are based on large training sets of experimental data and have been considered to provide the most reliable estimates. The results are summarized below:

- The QSAR models were able to identify 80-90% of the chemicals that actually tested as readily biodegradable, but (depending on the specific model) only 46-80% of the chemicals that actually tested as not biodegradable.
- The fraction of chemicals for which the QSAR predictions for acute toxicity "agreed" (defined as being within an order of magnitude of the test result) with the experimental data were: 4/5 of the chemicals for fish; 3/4 for invertebrates (specifically, crustaceans); and 2/3 for algae.
- The QSAR models were able to identify 95% of the chemicals that actually tested as negative for mutagenicity, but (depending on the specific model) only 60-80% of the chemicals that actually tested as mutagenic. (However, the comparison included so few substances that tested positive that the latter conclusion must be viewed as tentative.)

As with studies describing scientific validation efforts for specific QSAR models, these results suggest both the utility of certain QSARs but also some important limitations to their accuracy and reliability. As with the other methods discussed in this module, appropriate use of QSARs can play an important role in supplementing and extending the base of information available for use in chemical assessment — as long as their shortcomings are kept in mind and clearly communicated. While relying *solely* on QSAR-derived information will be sufficient only in relatively rare cases, such information considered as part of an integrated approach may well be able to help compensate for weaknesses or resolve conflicting results found in data derived from other methods, thereby strengthening the overall assessment.

Read-Across Methods (using chemical categories and analog chemicals): Both the OECD and U.S. EPA have developed relatively extensive guidance on the scientifically appropriate use of read across approaches in chemical categories, including: category definition and justification, the process to be followed for verifying the soundness of the category once data have been developed; and the specific methods to be used to assign specific hazard values to individual members of a category that have not been directly tested. This guidance also addresses read across from analog chemicals.⁶³

Even with clear guidance in place, careful expert review of assessments employing such methods is essential, as demonstrated by experience with chemical categories under the U.S. HPV Challenge Program, in which about 80% of all sponsored chemicals are being assessed as members of categories rather than individually. In comments filed on the initial industry submissions for these categories, U.S. EPA and public comments identified concerns or deficiencies in the category justifications in nearly half of the cases. For example, some categories were found to be overly broad or ill-defined, or an entire category or the inclusion of specific chemicals was found not to be supported by available data.⁶⁴

Presentation of the results of applying category-based approaches must be transparent. Assuming that a category is still found to be justified once all data development has been completed and evaluated, the final dataset needs not only to provide all required data elements for each category member, but also to clearly indicate those values that are extrapolated rather than experimentally measured, together with clear explanations as to how each value has been derived.

Weight of Evidence (WOE) Approaches: The largest concerns about the application of WOE are the absence of a rigorous definition of what constitutes WOE, or clear guidance and standards for the use of WOE and associated documentation and communication needs. A recent paper⁶⁵ provides empirical evidence for such concerns. An extensive survey of the published risk assessment literature found enormous variation in “uses” of WOE:

- 1) metaphorical, where WOE refers to a collection of studies or to an unspecified methodological approach;
- 2) methodological, where WOE points to established interpretative methodologies (e.g., systematic narrative review, meta-analysis, causal criteria, and/or quality criteria for toxicological studies) or where WOE means that “all” rather than some subset of the evidence is examined, or rarely, where WOE points to methods using quantitative weights for evidence; and
- 3) theoretical, where WOE serves as a label for a conceptual framework.

Clearly, if WOE approaches are to meet even basic tests for transparency, objectivity and accountability, a first priority must be addressing this lack of consistency — the multiplicity of definitions and uses; the multiplicity of weighting schemes and criteria for applying them; and a lack of clarity in defining the role of judgment in applying WOE approaches. At a minimum, full descriptions of any application of a WOE approach must be provided as to what information was actually considered, how it was weighed and why the conclusion is warranted. Ultimately, as the paper’s author notes, the goal is “to work toward a consensus on the meaning and methods of weight of evidence, such that a recognizable **standard** can be created and accepted.”

E N D N O T E S

- 1 For a more in-depth discussion of U.S. chemicals policy under the Toxic Substances Control Act (TSCA) and how it compares to that of the European Union (under its new REACH Regulation) and Canada under the Canadian Environmental Protection Act (CEPA), see Denison, R.A. 2007. *Not That Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals*. Environmental Defense, Washington, DC, at www.environmentaldefense.org/go/chempolicyreport.
- 2 Industrial chemicals, regulated under TSCA, typically exclude chemicals used only as pharmaceuticals, cosmetic ingredients, pesticides, or food additives, which are regulated under other statutes. The term is not intended to mean that such chemicals are used only in industry; many “industrial chemicals” are also present in consumer products. Except where otherwise noted, this paper’s use of the term “chemical” will typically refer to industrial chemicals.
- 3 Indeed, companies that “obtain information which reasonably supports the conclusion that such substance or mixture presents a substantial risk” are obligated to immediately report it to EPA. TSCA •8(e).
- 4 Government Accountability Office. 2005. Report GAO-05-458, Chemical Regulation—Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program, p. 18, at www.gao.gov/new.items/d061032t.pdf.
- 5 According to EPA, 67% of PMNs contain no test data; 85% of PMNs contain no health data; and more than 95% of PMNs contain no ecotoxicity data. The first two statistics are from U.S. EPA, Overview: Office of Pollution Prevention and Toxics Programs [OPPT], January 2007, prepared by OPPT (“OPPT Overview, 2007”), p. 8, at www.epa.gov/oppt/pubs/oppt101c2.pdf. The third statistic is from EPA, OPPT, Draft Q&A for the New Chemicals Program, undated, answer to Question 118-5, at www.epa.gov/opptintr/newchemicals/pubs/qanda-newchemicals.pdf.
- 6 One possible indication of these potential effects of early review is the fact that Notices of Commencement that signify the start of actual manufacturing are filed for only about half of notified chemicals that undergo PMN review; see EPA, OPPT Overview, 2007, *op. cit.*, p. 10.
- 7 See GAO, 2005, *op. cit.*, pp. 10-16.
- 8 EPA also must affirmatively demonstrate that insufficient data exist and that testing is needed to provide the data. To make the requisite findings, EPA often must first issue information reporting regulations under •8(a) and 8(d) to determine whether sufficient data exist, whether substantial production is occurring and whether significant exposure is likely. To develop and issue such rules can take several years or more and place significant strain on limited EPA resources.
- 9 EPA, OPPT Overview, 2007, *op. cit.*, p. 4.
- 10 EPA’s 1998 Data Availability Study is at www.epa.gov/chemrtk/pubs/general/hazchem.htm. The undertaking of that study and the launch of the HPV Challenge were spurred by a 1997 report, Toxic Ignorance, published by Environmental Defense, which examined 100 HPV chemicals and found that more than 70% of them lacked publicly available data sufficient to conduct even a screening-level hazard assessment. Toxic Ignorance and other Environmental Defense reports and information on the HPV Challenge are at www.environmentaldefense.org/subissue.cfm?subissue=14. The benchmark used to measure how “complete” available data are is the OECD’s SIDS — see endnote 12.
- 11 See EPA’s HPV Challenge web site, at www.epa.gov/chemrtk/index.htm.
- 12 The base set selected for the HPV Challenge is based on the SIDS, or Screening Information Data Set, developed by the Chemicals Committee of the Organization for Economic Cooperation and Development (OECD). For a list of the data elements, see EPA’s program guidance document, Determining the Adequacy of Existing Data, Appendix A, at www.epa.gov/chemrtk/pubs/general/datadfin.htm.

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- 13 For a full description of the HPV Challenge and what it has and has not accomplished, see Denison, R.A., High Hopes, Low Marks: A Final Report Card on the High Production Volume Chemical Challenge, July 2007, at www.environmentaldefense.org/hpvreportcard.
 - 14 See EPA's Office of Pesticides website at www.epa.gov/pesticides/regulating/index.htm#eval.
 - 15 See www.epa.gov/oppsrrd1/reregistration/reregistration_facts.htm.
 - 16 See EPA, TSCA Inventory Update Rule Amendments, *Federal Register*, 7 January 2003, Vol. 68, No. 4, pp. 847-906, at www.epa.gov/fedrgstr/EPA-TOX/2003/January/Day-07/t32909.htm.
 - 17 Certain chemicals on the TSCA Inventory are fully or partially exempted from IUR reporting. Full exemptions apply to most polymers, and also to chemicals that are: produced in small quantities for research and development; imported as part of an article; impurities, byproducts (under certain circumstances), or non-isolated intermediates; and manufactured by a small manufacturer as defined in the regulations. Partial reporting exemptions apply to certain petroleum processing streams, other chemicals deemed to be of "low current interest" and specifically listed in the regulations, and inorganic chemicals (the latter will be subject to full reporting starting in 2011). See EPA, Questions and Answers for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database, answers to questions 30-37, at www.epa.gov/opptintr/iur/pubs/guidance_qanda.pdf.
 - 18 This quantity was chosen to cover HPV chemicals, which are produced in amounts, *aggregated across all manufacturers*, of one million pounds per year or more.
 - 19 U.S. EPA, National Pollution Prevention and Toxics Advisory Committee (NPPTAC), Broader Issues Work Group, Initial Thought-Starter: How Can EPA More Efficiently Identify Potential Risks and Facilitate Risk Reduction Decisions for Non-HPV Existing Chemicals? Draft dated October 6, 2005, pp. 3-4, at www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf; and Environmental Defense comments on Proposed Rule, TSCA Inventory Update Reporting Revisions (70 Fed. Reg. 3658, 26 January 2005), Docket ID No. EPA-HQ-OPPT-2004-0106, accessible at www.regulations.gov (search for docket number).
 - 20 See EPA, EPA Authorities under TSCA, 2005, p. 23.
 - 21 EPA, OPPT Overview, 2007, *op. cit.*, p. 16. Statistics as of September 2006.
 - 22 See U.S. EPA, Toxics Release Inventory Reporting, Year 2005 Public Data Release, Summary of Key Findings, pp. 1-2, at www.epa.gov/tri/tridata/tri05/pdfs/Key_Findings.pdf.
 - 23 For 20 PBT chemicals, full reporting was previously required at any quantity of release or waste management; now, only the certification is required for facilities that manage up to 500 pounds annually of such PBTs as long as there is no environmental release. See 71 *Federal Register* 76937, December 22, 2006, at www.epa.gov/fedrgstr/EPA-TRI/2006/December/Day-22/tri21958.htm; and OMBWatch, Against the Public's Will, December 2006, p. 3, at www.ombwatch.org/info/TRICommentsReport.pdf. More recently, President Bush signed an Executive Order that would likely have the effect of exempting federal facilities from TRI reporting. While federal facility reporting is not required by the law that established the TRI, Clinton-era Executive Orders extended the requirement to such facilities. On January 26, 2007, President Bush signed a new Executive Order that has the effect of rescinding this requirement, although final resolution is awaiting clarifying guidance to be issued by the Council on Environmental Quality. See OMBWatch, Congress, White House Going in Opposite Directions on TRI, February 21, 2007, at www.ombwatch.org/article/articleview/3729/1/1?TopicID=1.
 - 24 See <http://toxics.usgs.gov/about.html>.
 - 25 See http://toxics.usgs.gov/highlights/pharm_watershed/ for examples of recent USGS studies.
 - 26 See http://www.clw.csiro.au/video_html/danakolpinSep04.html.
 - 27 A QSAR is a mathematical model that yields a quantitative estimate for a specific toxicological endpoint or other biological property for an untested chemical. QSARs are developed using a body of empirical data (termed a "training set") derived from analyzing or testing multiple chemicals for both a) physical-

chemical properties that correlate to specific structural features, and b) toxicological endpoints or other biological properties of interest. The quantitative relationship between these two sets of properties for the tested chemicals is then expressed in the form of an algorithm. The algorithm can in turn be used to estimate values for toxicological or other biological properties of an untested chemical, based on the extent of similarity in its chemical structure and/or physical-chemical properties relative to those chemicals in the training set.

28 “Read-across” (often also known as qualitative SAR) refers to methods in which values for an untested chemical are derived from tested chemicals, based on the extent of structural or functional similarity. The read-across method is usually applied in either of two ways:

- Within a category of structurally and/or functionally related chemicals, only some of which have been tested. An example of such a category is a group of fatty acids that differ only in the length of an attached carbon chain (e.g., C2, C4, C6, etc.). If, for a given endpoint, empirical values are available for the C2 and C6 category members but not for the C4 member, reading across can be done across these three chemicals to estimate that the value for C4 falls between the values for C2 and C6.
- Used to provide an endpoint value for an untested chemical by simply adopting the value for a tested “analog” (also known as a “surrogate”) chemical considered to be sufficiently closely related to it.

In both cases, testing-derived data for some chemicals are used to extrapolate, estimate, or provide data for “related” chemicals that have not been directly tested.

29 Measured physical-chemical data on a chemical are among the inputs to these models.

30 While expert judgment and the use of assumptions are not strictly to be viewed as sources of actual information, they effectively act as such and represent means of compensating for the lack of “hard” information. And they are widely used in practice where other information is not available, is considered too time-consuming, difficult or expensive to develop, etc. “Reasonable worst-case assumptions,” for example, are frequently used by government in assessing chemicals for which few data are available.

31 See EPA’s guidance documents for the HPV Challenge, at www.epa.gov/chemrtk/pubs/general/guidocs.htm.

32 See OECD’s Manual for Investigation of HPV Chemicals, at www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html.

33 REACH stands for Registration, Evaluation, Authorization and Restriction of Chemicals. See Annex XI, p. 371, at eurlex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf.

34 See *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*, Pursuant to Section 69 of the Canadian Environmental Protection Act, 1999. Co-published by Environment Canada and Health Canada. Version 2005 – EPS M-688, Section 8, at www.ec.gc.ca/substances/nsb/pdf/cpguidem688.pdf.

35 U.S. EPA, Overview: Office Of Pollution Prevention and Toxics Programs, 12/24/03 draft version 2, prepared by OPPT for the National Pollution Prevention and Toxics Advisory Committee, pp. 7-8, at www.epa.gov/oppt/pubs/oppt101c2.pdf.

36 See Health Canada, Proposed Integrated Framework for the Health-Related Components of Categorization of the Domestic Substances List under CEPA 1999, June 2005, Part C, p. 24, at www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/publi-comment/index_e.html.

37 Syracuse Research Corporation, Flame Retardant Alternatives, study conducted for the Washington State Departments of Ecology and Health, February 2006, at www.ecy.wa.gov/programs/eap/pbt/pbde/docs/flameRetard.pdf.

38 REACH, Article 13(1) and Annex XI, Section 3.

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- 39 Denison, R.A. Environmental Defense's perspective on policy issues related to exposure assessment, in OECD Series On Testing And Assessment, No. 51, Approaches to Exposure Assessment in OECD Member Countries: Report from the Policy Dialogue on Exposure Assessment in June 2005, Chemicals Committee, Organization for Economic Cooperation and Development, p. 109, at [applied1.oecd.org/olis/2006doc.nsf/linkto/ENV-JM-MONO\(2006\)5](http://applied1.oecd.org/olis/2006doc.nsf/linkto/ENV-JM-MONO(2006)5).
- 40 See www.epa.gov/opptintr/iur/.
- 41 Under the TSCA's Inventory Update Rule, producers and importers of industrial chemicals listed on the Inventory that make or import more than 25,000 pounds of a chemical per year must report production information to EPA once every five years. Until recently, this requirement applied to chemicals above 10,000 pounds/year and reporting was required once every four years. Based on production volume data reported for 1986, 1990, 1994, 1998 and 2002, EPA has found that as much as one-third of the chemicals reported on the TSCA Inventory Update appear and disappear between subsequent reporting cycles — that is, they are reported in one reporting cycle and not reported in the next, or vice versa — presumably because production falls below or rises above the reporting threshold, or ceases and restarts. See U.S. EPA, National Pollution Prevention and Toxics Advisory Committee (NPPTAC), Broader Issues Work Group, Initial Thought-Starter: How Can EPA More Efficiently Identify Potential Risks and Facilitate Risk Reduction Decisions for Non-HPV Existing Chemicals? Draft dated October 6, 2005, *op. cit.*, EPA's answer to question 2, pp. 3-4. Environmental Defense's analysis of these same data showed that, for about 40-50% of chemicals reported in both of any two sequential reporting cycles, their reported production volumes changed significantly from one cycle to the next, likely by one or more orders of magnitude. See Environmental Defense comments on Proposed Rule, TSCA Inventory Update Reporting Revisions (70 *Fed. Reg.* 3658, 26 January 2005), *op. cit.*
- 42 TSCA does not provide EPA with authority to require upfront testing of new chemicals on a routine basis.
- 43 EPA has indicated that a TSCA -4 rule can take between 2–10 years to promulgate and requires significant resources. GAO, 2005, *op. cit.*, p. 26.
- 44 Through the end of September 2005, EPA had negotiated about 300 Voluntary Testing Actions. EPA, OPPT Overview, 2007, *op. cit.*, p. 11.
- 45 TSCA, Section 4; and CEPA, Sections 71 and 72.
- 46 These requirements for existing chemicals are to be phased in over a period of 11 years of the effective date of REACH (June 2007), also based primarily on the production volume of the chemical. See REACH, Article 23.
- 47 REACH, Article 46.
- 48 See endnote 13.
- 49 See www.epa.gov/oppt/newchems/pubs/sustainablefutures.htm. PBT = persistent, bioaccumulative, and toxic.
- 50 See, e.g., Stiglitz, J.E. Information and the Change in the Paradigm in Economics, Part 1. *The American Economist*, 47:6-26. 2003.; Stiglitz, J.E. Information and the Change in the Paradigm in Economics, Part 2, *The American Economist*, 48:17-49, 2004, at <http://www2.gsb.columbia.edu/faculty/jstiglitz/papers.cfm>; and Stiglitz, J.E. *Globalization and Its Discontents*. New York: W.W. Norton & Company, Inc.: 73-74, 261n.2. 2003, all cited in Guth, J, Denison, R.A. and Sass, J. (2006) Background Paper #5, Require Comprehensive Safety Data for All Chemicals, at www.louisvillecharter.org/paper.safetydata.shtml.
- 51 This potential of REACH is explored in more detail in Lahl, U., "REACH – Assessment of the Political Agreement," 2006, at www.bmu.de/english/chemical_safety/downloads/doc/38542.php.
- 52 See, for example, EPA's Environmentally Preferable Purchasing (EPP) website at <http://www.epa.gov/epp/pubs/about/about.htm>.

- 53 See Department of Ecology website, www.ecy.wa.gov/programs/eap/pbt/pbtfaq.html.
- 54 See Department of Environmental Protection website at www.maine.gov/dep/mercury/products.htm.
- 55 These proposals are liberally adapted from a summary of Wagner, W. and Steinzor, R., eds. 2006. *Rescuing Science from Politics: Regulation and the Distortion of Scientific Research*, Cambridge University Press, summary at www.progressivereform.org/issue_science.cfm#rescue.
- 56 These concepts are more fully developed in: Denison, R.A. and Balbus, J.M. Environmental Defense Perspective on Integrated Approaches to Chemical Testing and Assessment, presented at the 39th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, OECD, 15-17 February, 2006, at www.oecd.org/dataoecd/19/34/36286018.pdf.
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MODULE 2

Sharing Knowledge about Chemicals: Policy Options for Facilitating Information Flow

■ RACHEL MASSEY

How does information about chemicals flow among government, firms, workers, and the public? How can policy-makers ensure that information reaches those who need it, when they need it?

In 1998, the California Department of Health Services received a physician's report describing the case of an automobile repair technician who had developed peripheral neuropathy (impairment of nerve function). The illness had been caused by the technician's exposure to n-hexane, an ingredient used in brake cleaners. After this initial report, other automotive technicians were found to be suffering from similar problems. n-Hexane has been recognized as a neurotoxicant since 1964.¹ Despite this fact, manufacturers began using hexane as a preferred alternative in brake cleaners after California adopted a regulation in 1990 discouraging the use of chlorinated solvents. Additional regulatory changes in 1997 led to the sale of hexane-acetone blends, a combination with even more potent neurotoxic effects.² Thus, a regulatory effort to address one set of chemical hazards led inadvertently to the creation of a new occupational health problem.³

In 2005, a 36-year-old man was awarded a \$2.7-million settlement for irreversible lung damage he had suffered over the course of two years working at a company producing microwaveable popcorn.⁴ Dozens of former workers at popcorn plants have filed similar suits. The workers suffer from bronchiolitis obliterans, a devastating and irreversible disease caused by exposure to diacetyl, an ingredient in artificial butter flavoring. The defendant is International Flavors and Flavorings Inc., which sold the flavoring to the companies where these workers were employed. In the lawsuits, workers argued that International Flavors and Fragrances Inc. failed to provide appropriate warnings to the companies purchasing and using butter flavoring, even though it possessed significant information about the hazards of breathing diacetyl. International Flavors and Flavorings Inc. adopted measures to protect its own workers, but did not pass these guidelines on to downstream users of the product.⁵

In 2007, RC2 Corporation, producer of a popular line of toys, Thomas the Tank Engine, recalled more than 1.5 million toys after learning that they were decorated with paint containing lead. The U.S. Consumer Product Safety Commission warned parents to take the toys away from their children immediately.⁶

The circumstances leading to each of these events were different, but all of these cases illustrate the importance of information for responsible decision-making about chemicals. In all of the cases, the health effects of the chemical in question were known, but that information was not available to, or used by, the right people at the right time to protect human health.

To avoid public health tragedies caused by chemical exposures, it is not sufficient to gather information about chemicals. That information must flow through the economy to all actors who make decisions about chemicals. 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. The information that is necessary for decision-making to protect human health and the environment may include, depending on the situation, information about hazard, exposure, uses, and availability of alternatives.

This module builds on the groundwork laid by Richard Denison's discussion of options for generating information about chemicals (see Module 1). Here, we consider the next step: once information exists, how does that information flow among government, firms, workers, and the general public? We examine existing initiatives and offer suggestions about how policy-makers can take action to improve information flow.

Table 1, following, summarizes the major existing policies that are discussed in this module, indicating the type of information dealt with by each and who produces and receives the information in each case.

Table 2 summarizes the range of actions that states can take to improve the status quo, whether by requiring information disclosure, facilitating communication, or managing data effectively. These options are discussed in detail in the modules that follow.

TABLE 1 Existing Policies for Ensuring or Facilitating Information Flow

Policy Option	Information flows from	Information flows to	Type of information	Mandatory/voluntary
REACH–registration requirement	Firms	Government, other firms, and public (except as limited by confidential business information [CBI])	<ul style="list-style-type: none"> Inherent properties How chemical is used Risk management guidelines 	Mandatory
TSCA–new chemicals	Firms	Government	<ul style="list-style-type: none"> Inherent properties 	Mandatory
HPV Challenge program	Firms	Government, other firms, and public	<ul style="list-style-type: none"> Inherent properties 	Voluntary
Massachusetts Toxics Use Reduction Act	Firms	Government, other firms, and public (except as limited by CBI)	<ul style="list-style-type: none"> What chemicals are used Quantities used Quantities released 	Mandatory
	Government	Firms	<ul style="list-style-type: none"> Safer alternatives Techniques for reducing toxics 	Mandatory (via TUR planners); Voluntary (via technical assistance)
New Jersey Worker & Community Right-to-Know Act	Firms	Government, other firms, workers and public (except as limited by CBI)	<ul style="list-style-type: none"> What chemicals are used/stored Quantities used/ stored 	Mandatory
California Proposition 65	Firms	Government, other firms, workers and public	<ul style="list-style-type: none"> Ingredients/ health effects 	Mandatory

TABLE 2 What States Can Do: Options for Improving Chemical Information Flow

<ul style="list-style-type: none"> Require firms to submit information on chemical hazards (including information that firms are required to submit to government authorities outside the US). Require warnings or labels identifying chronic health hazards from chemicals in products or work places. Require firms to provide information on chemical use: <ul style="list-style-type: none"> Following the model of the registration requirements under REACH, or Following the toxics use reporting model under TURA. Adopt best practices for management of confidential business information. Restrict the use of priority toxic substances in products or require disclosure of priority toxic substances, creating incentives for manufacturers to obtain information from suppliers (model: RoHS). Require or encourage firms to submit alternatives assessments or substitution analyses for priority toxic substances. Strengthen MSDS requirements for public-sector work sites. Require firms to disclose chemical ingredients of products via labeling or registry requirements. <ul style="list-style-type: none"> Create a registry of chemical ingredients of products (mandatory or voluntary) <ul style="list-style-type: none"> Open to the public, or Managed by government, including confidential information. Develop infrastructure for managing chemical information collected by other governments (for example, information submitted under REACH). Convene consortia for voluntary information sharing within supply chains. Promote use of the Chemical Management Services model.
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OBSTACLES TO INFORMATION SHARING

In an ideal world, industries would produce, use, and sell chemicals that are as safe as possible for human health and the environment. Buyers of a product would be able to distinguish between a dangerous product and a safer one. Product manufacturers would choose the safest possible components; and component producers would distinguish among more or less dangerous chemicals to use in creating those components. But barriers to information flow through the supply chain make it difficult to make choices of this kind. In many instances, it is difficult or impossible to identify the safer product, component, or ingredient.

Communication deficits affect actors at every level of the supply chain. Chemical manufacturers frequently lack information about how their products will be used.⁷ Meanwhile, downstream users of chemicals may wish to purchase and use safer chemicals but lack the information that would allow them to select those chemicals. A 2002 study commissioned by the European chemicals industry association, Cefic, found serious gaps in information flow up and down the supply chain, as well as horizontally among firms manufacturing the same products.⁸

Professional users and individual consumers of products containing chemicals also are ill informed. Labeling requirements exist for some products, but they do not necessarily provide sufficient information to allow users to protect their own or their customers' health.⁹

Under the current regulatory system in the U.S., there are multiple disincentives for sharing information about chemicals.¹⁰ They include:

- Competition among manufacturers: Chemical manufacturers that actively seek information on how their chemical is handled and used could potentially lose business to manufacturers who ask fewer questions.
- Confidential business information: Both chemical manufacturers and downstream users may wish to protect information on production processes and on sales.
- Liability: Companies may withhold hazard information, or avoid gathering hazard information in the first place, in an effort to avoid responsibility for health or environmental problems caused by their products.
- Supply chain dynamics: "Many chemicals are sold and bought through intermediate distributors or brokers who as a rule have even less incentive to share information upstream or downstream."¹¹

MANDATORY VS. VOLUNTARY PROGRAMS

In some instances, both mandatory and voluntary program options exist to achieve a given policy goal. It is worth noting that mandatory and voluntary approaches can complement one another.

Mandatory requirements can serve as important motivators for participation in voluntary programs. For example, the industry consortia described in the case studies in this module were voluntary, but industry participation was motivated in part by European requirements to eliminate certain toxic substances from electrical and electronic equipment. A voluntary program can also be designed in conjunction with a backstop mandatory program that is triggered if the voluntary program does not achieve the desired results. For example, a voluntary data collection program could be paired with a backstop mandatory data collection program.

Voluntary programs can also serve as preparation for the introduction of mandatory measures. Voluntary participation in an initiative to increase information sharing can serve as a test case, demonstrating the viability of a given approach or providing an opportunity to work out implementation details. For example, the European chemical industry association, Cefic, voluntarily carried out a series of trials to determine whether the REACH requirements were feasible, and insights from these exercises helped to inform the final legislation.

TYPES OF INFORMATION SHARING: INHERENT PROPERTIES, USE, AND INGREDIENTS

Information sharing requirements may deal with information about the inherent properties of a chemical; about how a chemical is used; or about the ingredients or contents of a mixture or product.

Information About Inherent Properties

Firms are required to provide some information about inherent properties of chemicals to the U.S. government under the new substances provisions of the Toxic Substances Control Act (TSCA). Limitations of these provisions are discussed in the module on information generation.

The primary vehicle for communication among firms about the inherent properties of a chemical is the Material Safety Data Sheet (MSDS). The MSDS provides basic physical data on a chemical, such as melting point, boiling point, and flash point, as well as information on health effects, storage guidelines, the need for protective equipment, procedures for handling spills, and other information. Under OSHA regulations, the original manufacturer or importer of any hazardous chemical must create an MSDS for that chemical, and must provide the MSDS to any commercial customer or distributor, who in turn must pass on the MSDS to any other firm to which it sells the chemical.¹²

Weaknesses of the MSDS system include the fact that MSDSs are frequently incomplete or inaccurate, they may lack important information about guidelines for controlling exposure, they are not always provided to the workers who may be exposed to the chemical in question, and they are created by the manufacturer and may not be subject to significant scrutiny by a government authority. MSDSs may be inconsistent; multiple firms selling the same chemical may provide different information in their MSDSs.

Federal OSHA regulations apply only to the private sector. Individual states establish occupational safety and health rules for public sector employees under their jurisdiction, and may be authorized to promulgate regulations more protective than federal OSHA standards. This authority creates an opportunity for action at the state level to increase the availability of information about chemicals. Specifically, states can require information on an MSDS for public-sector work sites that goes beyond the federal requirements for private-sector work sites.

For example, Pennsylvania has adopted requirements for MSDSs for public-sector work sites that are more extensive than the corresponding OSHA requirements. OSHA regulations require that MSDSs include information about hazardous ingredients that constitute 1% or more of a mixture; for carcinogens, the threshold is 0.1%.¹³ Going beyond these requirements, Pennsylvania requires that MSDSs for public sector work sites list *all* chemicals that comprise 3% or more of a mixture. Chemicals included on the state's list of "hazardous substances" must be listed if they comprise 1% or more of the mixture; and "special hazardous substances" must be listed if they comprise 0.01% or more of the mixture.¹⁴ Thus, MSDSs for products used at public-sector work sites in Pennsylvania contain more information than MSDSs that only meet the federal OSHA standards. By adopting similar requirements, other states could help to make this protocol a reality for a wider range of products.

The information in an MSDS is targeted primarily at workers. However, MSDSs are also used by other constituencies. Businesses may use the MSDS to research substitute products that may be better for the environment or public health in addition to being safer for employee health. Many MSDSs are internet available and consumers may look to the MSDS to provide product information beyond what is provided on the label.

Thus, any effort to make the information in MSDSs more complete or extensive will benefit more than workers. The National Institutes of Health/National Library of Medicine has developed and maintains a Household Products Database. This database uses the information in MSDSs, along with product labels and other publicly available information, to "allow scientists and consumers to research products based on chemical ingredients." It is searchable by product category, by ingredient, or by health effects. It can be used to determine the chemical ingredients in specific product brands; to identify products that contain a specific chemical; to identify the manufacturer of a specific product brand; to identify the acute and chronic effects of chemical ingredients in a specific brand; and to answer other, similar questions about chemicals in products.¹⁵

The Globally Harmonized System for Classification and Labeling of Chemicals (GHS) is an United Nations effort to improve information sharing by harmonizing requirements for safety data sheets across countries. The GHS specifies criteria for "classifying substances and mixtures according to their health, environmental, and physical hazards," as well as "harmonized hazard communication elements, including requirements for labeling and safety data sheets."¹⁶ By standardizing information requirements, the GHS system has the potential to improve significantly on the existing MSDS system in the U.S. The GHS system also offers the advantage that it synthesizes information about a chemical, classifying chemicals according to the type and level of hazard they present.

The GHS could also create new opportunities for state governments.¹⁷ The GHS will primarily affect the criteria that industry will use to classify, develop MSDSs for, and label chemicals or products. However, governments could choose to use the GHS criteria to analyze hazard data themselves as well, and could communicate the results through their databases. For example, a government agency could examine the data produced by the HPV Challenge Program (described below) on reproductive toxicity and determine which HPV chemicals meet the criteria for being a category 1 reproductive toxicant, and then include that classification in the HPV database. In other words, government could use the GHS to help interpret “raw” data. This is an activity that could be carried out at the federal or the state level.

Information about Use

Firms may provide information to one another, or to government and the public, on how they are using a chemical, including information on the industrial processes that rely on it and the products into which it is incorporated. This information may be important in determining the extent of human exposure to the chemical. Firms also may provide information on what chemicals they use and in what quantities, without specifying what purpose the chemicals serve.

In Europe, REACH requires that chemical manufacturers and importers provide information to government authorities on how chemicals will be used. This requires that manufacturers and importers gather information from downstream users of the chemicals they produce. This model is discussed in the case study on REACH.

In general, downstream users of chemicals in the U.S. are not required to provide use information to suppliers upstream, or to government, with some exceptions. Firms using toxic chemicals are required to submit some limited information about use as part of the Toxics Release Inventory (TRI) under the federal Emergency Planning and Community Right-to-know Act (EPCRA).

In addition, some states require additional reporting on chemical uses, as discussed below in the sections on Massachusetts and New Jersey.

Information about Ingredients or Contents

Under the current regulatory system in the U.S., labeling and ingredient disclosure requirements exist for some categories of products containing chemicals and are absent for others. As a result, both professional users and individual consumers of products containing chemicals frequently lack information about what those products contain, and how those ingredients may affect their health.

U.S. regulations create labeling requirements for pesticides and cosmetics and some other products containing chemicals, as well as for drugs and food. In this section, we list key statutory requirements for pesticides, cosmetics, and other consumer products. Food and drug labeling requirements are outside the scope of the present discussion.

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- Under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), EPA prescribes labeling requirements for all pesticides. Labels must specify pesticide active ingredients; so-called “inert” ingredients do not have to be disclosed, even if they are known to be toxic.
 - Under the Federal Food, Drug, and Cosmetic (FD&C) Act, ingredients must be listed on the label of cosmetics that are distributed for retail sale to consumers. Cosmetics used by professionals, and not sold for use at home, are exempt from this requirement. In addition to the ingredient declaration, “cosmetics which may be hazardous to consumers when misused must bear appropriate label warnings and adequate directions for safe use.”¹⁸
 - Under TSCA, the EPA has the authority to require hazard-warning labels for chemicals, but only when EPA is able to demonstrate that the chemical in question poses an “unreasonable risk” to human health or the environment. EPA has used this authority for a handful of chemicals to date; they include PCBs, asbestos, hexavalent chromium, and acrylamide grout. Products containing these chemicals must bear a label that names the chemical and describes its health effects and use restrictions.¹⁹
 - The Consumer Product Safety Commission (CPSC) is responsible for labeling requirements for certain products containing chemicals. For example, the Federal Hazardous Substances Act gives the CPSC jurisdiction over “potentially injurious consumer goods presenting hazards such as toxicity, combustion, radioactivity,” and other hazards; and the Poison Prevention Packaging Act authorizes the CPSC to set labeling and packaging requirements to protect children from “potential serious harm.”²⁰ However, the CPSC has used its authority almost exclusively to address products containing acutely toxic chemicals. There is no general labeling and disclosure requirement for products containing chemicals that pose chronic health hazards.
 - OSHA’s Hazard Communication System requires chemical manufacturers and importers to label their products and provide material safety data sheets (MSDSs) to downstream users. OSHA also requires that “all employers with hazardous chemicals in their workplaces must have labels and MSDSs for their exposed workers, and train them to handle the chemicals appropriately.”²¹

This patchwork of statutory requirements leaves open several important gaps. Many consumer products, as well as products used professionally by small businesses, are not subject to any requirement to list ingredients or to provide information on health effects. A manufacturer of paint, glue, or brake cleaner, for example, has no obligation to list or report the ingredients of these products on the label (although an MSDS would have to be provided to firms using the product). Similarly, a manufacturer of an electronic product containing cadmium, jewelry containing lead, or a plastic toy containing a toxic plasticizer has no legal duty to disclose these ingredients either to firms downstream in the supply chain or to individual consumers.

Some regulations create an incentive for the buyer of a product containing a chemical to obtain chemical information from the manufacturer. In the European Union (EU), for example, the Restriction on Hazardous Substances (RoHS) Directive prohibits the sale of electrical or electronic equipment containing certain toxic chemicals. This requirement makes it necessary for manufacturers of electrical and electronic equipment to obtain information from their suppliers upstream about

the chemicals used in producing individual components of the equipment. An advantage of the RoHS Directive is that it has motivated electronics manufacturers to greatly increase their communication up and down the supply chain (see the case study of the electronics industry later in this module).

Demand for Information: Who Needs What?

Different types of information are needed, depending on who the user is and how the information will be used. For example, an epidemiologist looking for links between asthma and chemicals in cleaning products might benefit most from a database that identifies all of the consumer products containing a specific chemical. Meanwhile, an individual consumer who wishes to avoid cleaning products linked to asthma might benefit most from product labeling that identifies the health effects of product ingredients.

For some situations, users of chemical information primarily need interpretive information, answering questions such as, “Is this chemical hazardous?” or “Should this product be kept away from children?” For other situations, information users need a deeper level of information, answering questions such as, “Is this chemical bioaccumulative?” or “Does this product contain neurotoxic chemicals?” For still other uses, the underlying data are necessary to answer questions such as, “What is the bioaccumulation factor for this chemical?”

Ideally, information should be provided as a nested set, with broad interpretive classifications as the first level, and additional information, including the raw data underlying the classification, available in additional levels. To maintain transparency, it is essential to provide access to all levels of information. Thus, for example, it is not sufficient to label a product as “hazardous” without providing information on its chemical ingredients. Similarly, along with a designation such as “probable human carcinogen,” access to the test data underlying that designation should be provided as well. One good model of a database that provides information as a nested dataset is the system developed by the Swedish pharmaceuticals industry to track the environmental effects of pharmaceutical chemicals.²²

RIGHT-TO-KNOW AND CONFIDENTIAL BUSINESS INFORMATION

Right-to-know legislation creates an obligation for firms or government to release certain information to the public. Such legislation can be designed in several possible ways. It can be written to create an affirmative obligation for firms to provide information to the public, whether in the form of labeling, placing information on the internet, or other methods of disseminating information. Alternatively, right-to-know legislation can simply place limits on what information may be withheld.

In the U.S., right-to-know legislation has played an important role in chemicals policy both at the federal and at the state level. Under the Emergency Planning and Community Right-to-know

Act (EPCRA), companies must release information about emissions of toxic chemicals to water, land, and air for inclusion in the TRI. TRI data are available on the internet, and make it possible for the public to monitor chemical releases to the environment. In addition to providing information on chemical releases, TRI includes some information on chemical uses.²³

Other federal legislation containing right-to-know provisions includes the 1996 Safe Drinking Water Act amendments that require water utilities to provide their customers with information about contaminants in their water, and amendments to the Clean Air Act that require “facilities using or storing large quantities of dangerous chemicals to file Risk Management Plans (RMPs), which evaluate risks and establish emergency plans for accidents.”²⁴

Numerous legislative initiatives at the state level have taken the right-to-know concept further, creating additional disclosure requirements. 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. Massachusetts and New Jersey require facilities to provide information on their use of toxic chemicals.²⁵

Right-to-know legislation can create incentives for firms to improve their environmental profile. The publicity surrounding TRI data has created strong incentives for facilities to reduce their toxic emissions. Public availability of information about toxics in products can help to bring market forces into play, allowing consumers to express preferences and creating competitive pressures for companies to develop safer products. Public availability of information about toxics at the facility level also makes it possible for investors to express a preference for good environmental performance.

Going a step further, REACH for the first time creates an affirmative obligation for firms to make information about chemical **hazards** readily available to the public via the internet. Over time, this provision could have effects as profound as those that have resulted from TRI in the U.S. The requirement to provide hazard information to the public is likely to create incentives for companies to invest in and promote chemicals that are inherently less hazardous.

Confidential Business Information

While right-to-know legislation ensures that certain information will be available to the public, Confidential Business Information (CBI) provisions protect certain information from public release. Provisions governing CBI can significantly affect the flow of information from firms to government, to other firms, and to the public.

In designing CBI provisions, two questions must be considered: what categories of information are considered eligible for CBI status and what privileges are conferred by CBI status when it is granted. U.S. law places few restrictions on firms’ ability to claim CBI; the rules in Europe and Canada place more limits on what information may be kept secret and under what circumstances that secrecy applies.

Under U.S. law, a firm may claim CBI status for information about a chemical's "production, processing, use, and presence in products." Hazard information itself is generally not eligible for the CBI designation, but since the firm and chemical identity can be designated as confidential, this information is of little use to other firms or to the public. TSCA prohibits EPA from sharing CBI with anyone, including state governments.²⁶

In Canada, firms making CBI claims for new chemicals must submit a justification, which the government must review and accept or deny. "CBI claims do not expire or require reassertion." "CEPA [the Canadian EPA] provides broad authority for the sharing of CBI with other governments, domestic and foreign."²⁷

REACH distinguishes among categories of information that must be made public, will generally be considered CBI, or must be made public unless the firm successfully makes the case for CBI protection. For new chemicals, "the chemical identity can be claimed as CBI for up to six years; otherwise, REACH does not provide for the expiration of CBI status." "REACH [also] provides broad authority to share CBI with other domestic and foreign governments."²⁸

The advocacy organization Environmental Defense has recommended best practices for CBI provisions, including the following:²⁹

- "Health and safety information should never be eligible for CBI protection."
- Firms should be required to "specify exactly what information is to be kept confidential," and should have to provide a justification for the request.
- Government should have to review and accept or deny the CBI request.
- There should be a time limit on CBI claims granted.
- Government should be able to disclose CBI when it is in the public interest. If government rejects a confidentiality request for submitted information, it should be able to disclose that information to the public "after providing a reasonable opportunity for the submitter to rectify the request."
- "Workers should have access to all available information, whether or not CBI-protected ... for any substance with which they work or to which they could be exposed during work."
- Other governments ... should be given access to CBI," and "governments should ensure they have access to chemical information, including CBI, that is submitted to other governments."
- Finally, "policies should include explicit requirements that government make readily and publicly available as much information as possible about chemicals as well as documentation of decisions and the basis for them."

There are limits to how much initiative can be taken at the state level with regard to CBI. If information is protected as CBI at the federal level, state government is not in a position to obtain, or share, that information. One area in which state government can take the initiative is in obtaining and using any eligible information gathered by foreign governments.

States can also work to adopt best practices for management of data they collect themselves. For example, they can require that any application for trade secret protection be accompanied by a thorough justification of the request, which the state must accept or reject; and they can place a time limit on any trade secret protection that they do grant.

The Massachusetts Toxics Use Reduction Act may provide a partial model for management of confidential business information at the state level. Under TURA, companies may request that their chemical use data be kept confidential, but they must specifically apply for CBI status in each case.³⁰

PRODUCT REGISTRIES

One way to provide information to government, firms, and the public on chemical ingredients in products, and their health effects, is to create a product registry. Below we discuss two mandatory product registries — one dealing with a single chemical, the other with multiple chemicals — and one voluntary product registry.

The Interstate Mercury Education and Reduction Clearinghouse (IMERC) is a collaborative project of thirteen states. It was launched in 2001 by the Northeast Waste Management Officials' Association (NEWMOA) to provide technical and programmatic support “to states that have enacted mercury education and reduction legislation,” and to serve as a “single point of contact for industry and the public for information on mercury-added products and member states’ mercury education and reduction programs.”³¹

One element of IMERC is a Mercury-Added Products Database. The states of Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont have adopted legislation requiring firms selling mercury-added products to submit information to this centralized database. The database provides information for “consumers, recyclers, policy makers, and others” about “the amount and purpose of mercury in consumer products.” It can be used to identify mercury-added products; find out the amount of mercury in a specific product; identify manufacturers of mercury-added products; and answer other, related questions. The database is open to the public and is searchable by sector, product category, or manufacturer, or level of mercury content.³²

The Swedish Chemicals Inspectorate maintains the Swedish Products Register, a large database of information on products containing chemicals. Whereas the IMERC database focuses on a single chemical, the Swedish Products Register contains information on many chemicals. A total of 2,500 companies have submitted information to the Register, covering about 120,000 products, and identifying more than 16,000 chemicals in those products. Firms are required to provide information to the register, and to pay a fee, if they manufacture or import more than 1 ton of eligible products.³³

The registration must include a range of information, including chemical quantities, industrial categories, and health effects. The Chemicals Inspectorate uses the information to inform a wide range of analyses. The register is used primarily for government purposes, but other governments, organizations, and individuals may request information as well. Because the register includes a large amount of confidential information, only registry staff has access to the database, and each request for information is evaluated on a case-by-case basis, taking confidentiality requirements into account.³⁴

A voluntary approach to achieve a similar goal is exemplified in the “CleanGredients” database, a resource created for the US EPA Design for the Environment program that allows for voluntary listing of chemicals in institutional and industrial cleaning products.³⁵ This approach relies on market drivers, creating an incentive for manufacturers to list product ingredients in order to gain or retain customers.

MANDATORY INFORMATION SHARING: REGULATORY CASE STUDIES

A. Information Sharing under REACH

The new European chemicals regulation, REACH, is designed to improve information flow in multiple dimensions. It mandates information sharing about both chemical hazards and chemical uses. Its requirements affect communication among firms, between firms and government agencies, and between firms and the public.

Under REACH, manufacturers and importers of chemicals will provide information on chemical hazards and control measures to downstream users. At the same time, downstream users will provide information to suppliers upstream about chemical uses and exposures. The aim is to create a system that fosters on-going dialogue about both hazard and exposure.

Public Access to Chemical Information under REACH: Under REACH, all information submitted by firms will be compiled in a database managed by the central European Chemicals Agency. Some of this information will be freely available to the public. Other information will be accessible to the public in response to specific requests. Finally, some information will be considered confidential business information and will not be publicly available.³⁶

Specifically, the following information will be publicly available on the internet: name, classification and labeling, physicochemical data including information on pathways and environmental fate; results of each toxicological and ecotoxicological study; any derived no-effect level or predicted no-effect concentration; guidance on safe use; and, for some chemicals, analytical methods for detecting direct human exposures or discharge of the chemical to the environment. In addition, the following information also will be publicly available, except when the firm submitting the information successfully makes the case for keeping it confidential: information (where relevant)

on impurities or additives; total tonnage band within which a substance has been registered; summaries of the studies whose results are noted in the set of information listed above; other information contained in the safety data sheet; trade name(s); and other items.³⁷

This affirmative duty of public disclosure of information, with its emphasis on maximizing the amount of information freely available on the internet, is potentially one of the most important aspects of REACH. Access to information means that many other actors, outside government and outside an individual supply chain, also can use this information to make sound decisions about chemical use and exposure.

Chemical Safety Reports: Under REACH, a firm that manufactures or imports a chemical above 10 tons per year must submit a “chemical safety report” (CSR) to the central European Chemicals Agency. The CSR is a tool for providing information about a chemical both to government agencies and to downstream users. It includes “the hazard and risk assessment of the substance for specified (‘identified’) uses and how the risks posed by the chemical can be ‘adequately controlled’ for these uses. One of the outputs of the assessment is either an ‘exposure scenario’ or a ‘use and exposure category.’ This is a summary of the use(s) and appropriate risk management measures which is communicated to downstream users as an annex to the (material) safety data sheet (SDS).”³⁸ An advantage to the CSR requirement is that it places responsibility on the chemical manufacturer or importer for defining safe use conditions.

Data Sharing Among Registrants: REACH contains an innovative provision that requires companies to share hazard data with one another when animal testing is involved. REACH aims to minimize animal testing, even while promoting the collection of information on health effects of chemicals. Thus, in any case in which REACH requires a company to conduct testing on vertebrate animals, the legislation also requires the company to share the resulting data. In this way, the regulation avoids any unnecessary duplication of animal testing.

Under REACH, when a company is required to share data with others, it also receives monetary compensation for doing so. This provision helps to create a system in which information about chemicals has economic value. Placing a monetary value on information helps to create an incentive in favor of information generation and sharing. U.S. pesticide law also includes a data compensation requirement, which offers similar advantages.

Advantages to the data sharing requirements under REACH include the following:

- Data has a monetary value, increasing the incentive to collect data.
- REACH promotes sharing of data across companies, avoiding situations in which one company has full information about a chemical’s hazards, while another firm lacks this information.
- REACH uses information sharing provisions to avoid unnecessary animal testing. In addition to sparing animals from suffering, this means that monetary resources are not wasted on redundant tests.

Substitution Analysis: Under the authorization provision, for Substances of Very High Concern (SVHC), firms applying for authorization must investigate the availability of alternatives to the chemical in question, and must develop a substitution plan and time line if a viable alternative exists. By requiring companies to produce substitution plans, this provision has the potential to facilitate the transfer of important information from firms to government, not only about chemical hazards, but also about possible safer substitutes.

B. Chemicals Policies in Massachusetts and New Jersey

The Massachusetts Toxics Use Reduction Act (TURA) is an example of legislation that requires companies to provide certain information to the state and to the public about their use of chemicals. Under TURA, any company that uses toxic chemicals above a specified threshold (25,000 lbs/yr, 10,000 lbs/yr, or 1,000 lbs/yr, depending on the chemical and how it is being used), and that has 10 or more employees, must report to the state annually on the amount of each toxic chemical used. In addition, firms must prepare biannual toxics use reduction plans, specifying the opportunities that exist for reducing use of toxic chemicals in the facility.

Some of the information generated under TURA becomes available only to the state, while other information is available to the public. Specifically, the company's Toxics Use Reduction plan is held on file at the company and can be examined by state officials in spot checks. Data on the amount of toxics used by a company, broken out by category (use, byproduct, shipped in product, and on-site release) is freely available to the public on the internet.

Finally, TURA creates an opportunity for information flow *from* the state *to* companies. The state trains and certifies Toxics Use Reduction planners. These planners in turn work with the companies, bringing them state-of-the-art new information on options and techniques for reducing toxics. Firms are required to have their toxics use reduction plans certified by toxics use reduction planners, so contact between firms and these trained planners is mandatory. In addition, firms have the option to request confidential on-site assistance from the program's Office of Technical Assistance; thus, there is an additional voluntary component of information transfer from government to firms.

For some industries, TURA also increases communication in the supply chain. Companies that purchase products or mixtures containing toxic chemicals from other companies have to communicate with their suppliers in order to fulfill their own reporting and planning obligations.

The information sharing requirement under TURA differs from reporting requirements in most of the U.S. because it considers all uses of a chemical, including chemicals that are incorporated into a product, rather than just considering emissions. The requirement to report on all uses of listed toxic chemicals makes it possible for the state to track progress over time in reducing the use of targeted chemicals. It also facilitates internal planning and monitoring within companies. Finally, this requirement also makes it possible for citizens to monitor and assess progress in reducing toxics over time.

The New Jersey Worker and Community Right-to-Know Act provides for an annual inventory of toxic chemicals produced, used, or stored at New Jersey businesses and agencies. An annual survey of public and private employees generates this information, which is “available to the public and to emergency responders such as police and fire departments.” The information is also “used to supplement other regulatory programs within the state and to facilitate” emergency planning.³⁹

New Jersey also has a mandatory planning requirement. Similar to TURA, the New Jersey Pollution Prevention Act requires companies to develop Pollution Prevention Plans, without requiring the facilities to implement these plans. Plans must be updated every five years.⁴⁰

VOLUNTARY INFORMATION SHARING: NON-REGULATORY CASE STUDIES

In this section, we look at non-regulatory options for improving information sharing about chemicals. They include facilitating the formation of voluntary industry consortia, encouraging industry to collaborate in creating databases of chemical information, and promoting the model of chemical management services.

A. Industry Consortia: Case Studies

Information sharing can be enhanced through programs that bring together representatives of firms that might not ordinarily share information with one another. A consortium can facilitate horizontal information transfer, bringing together multiple firms that perform the same function. For example, under REACH, multiple suppliers of one chemical are encouraged to form consortia to collaborate in submitting information about the chemical to the European Chemicals Agency. In the U.S., chemical manufacturers have formed consortia to produce data for the HPV Challenge program (described in section B, below).

In industry consortia, companies at different points in the supply chain can work together to improve the environmental and health profile of a product. In a consortium, information about chemical uses and alternatives flows up and down the supply chain, facilitating innovation. Actors outside the industry can serve as network conveners, helping such a consortium to form and providing support for its work.

Information Sharing and Collaboration in the Electronics Supply Chain:⁴¹ The EU’s RoHS Directive restricts the use of several toxic substances, including lead and cadmium, in electrical and electronic equipment sold in the EU. The adoption of this legislation created new challenges for the electronics industry, and provided an incentive for firms to begin communicating with one another about the chemicals used in their products and components. It also created an incentive for companies to start thinking creatively about how to develop, test, and introduce products and components made with safer materials.

Identifying Constituents: The adoption of RoHS made it necessary for U.S. manufacturers of electrical and electronic equipment to find out what chemicals were present in their products. This need required communicating with suppliers upstream. Many manufacturers developed questionnaires asking suppliers for information on chemicals contained in the components they produced. In the early stages of the process, each questionnaire had its own format, so “suppliers spent significant time and resources to complete them.”

Responding to the lack of standardization, representatives of a number of electronics industry associations worked together to develop the Joint Industry Guide for Material Composition Declaration for Electronics Products (JIG). This document establishes “a standardized list of materials suppliers must disclose when present in products and components provided to electrical and electronic equipment manufacturers.”

The creation of the JIG has streamlined communication down the supply chain about chemical constituents in electrical and electronic components. The materials declaration process, previously a disorganized ad hoc process, has now become a recognized component of communications between supplier and purchaser. Developing this system required a significant investment on the part of manufacturers, but has paid off as a streamlined transparent system.

Assessing Performance of Alternatives: While developing a system to determine and track the constituent chemicals in electronic equipment and components, the electronics industry also worked on developing viable alternatives to equipment containing toxic substances targeted by the RoHS Directive. Representatives of the industry undertook a number of collaborative efforts to bring together personnel from each link in the electronics supply chain, and collectively to develop and test the performance of electronics made with alternative materials.

The electronics supply chain includes material suppliers (producing solder paste, ceramics for components, and board materials); component suppliers (producing chips, capacitors, and other components); board manufacturers; board assemblers; and original equipment manufacturers (OEMs). Other important entities that interact with the supply chain and have participated in consortium activities include university researchers, regulators, and certifying agencies.

Several industry consortia were formed at the national level. They work to generate, collect, organize, and disseminate information on options for producing electronic products without restricted chemicals. In some consortia, companies have worked together intensively to test alternative products.

These national consortia are geared primarily toward participation by large electronics manufacturers and the results of their research are available only to members. In Massachusetts, and later in the New England region as a whole, the state’s Toxics Use Reduction Institute facilitated information sharing for local companies and northeastern facilities of the larger national companies. This effort is now known as the New England Lead Free Electronics Consortium. The consortium

provides a forum in which companies throughout the supply chain can work together to develop lead-free electronic products and collaborate in testing their efficacy and reliability. Consortium members made a commitment from the outset to make all of their research results publicly available. The consortium includes representatives from each link in the supply chain for production of printed wiring boards. Its members work together with the goal of achieving a level of reliability with lead-free solder joints comparable to that of solder joints containing lead.

Wire and Cable Supply Chain:⁴² In related activities, the Massachusetts Toxics Use Reduction Institute also has helped to convene a consortium of firms involved in the coated wire and cable supply chain. PVC (polyvinyl chloride) plastic used to coat wire and cable is often stabilized with lead or cadmium. It also may contain toxic plasticizers and flame retardants. The Institute has worked with Massachusetts producers to create opportunities for information sharing with the goal of developing safer wire and cable coatings that do not contain these toxic chemicals. Like the activities of the electronics industry, the activities were motivated in part by the need for U.S. companies to achieve compliance with RoHS.

The coated wire and cable supply chain is composed of four principal links: resin manufacture, additive manufacture, compounding, and extruding.⁴³ Resin manufacturers and additive manufacturers produce the materials from which wire and cable coatings will be made. Compounders purchase resins and additives and combine them in custom formulations. Finally, extruders coat metal wires with the custom formulations of resins, producing finished wire and cable.

The competitive pressures affecting the coated wire and cable industry differ from those affecting the electronics industry. For manufacturers of electrical and electronic equipment, sharing information on the material content of their components is not a significant competitive concern; competition occurs primarily on other design aspects. In contrast, the specific formulation of the plastic used in wire and cable coatings is important information from the perspective of competition, so firms may be more reluctant to share this information. While the New England lead-free electronics project worked to build and test prototype lead-free models, the aim of the coated wire and cable consortium was simply to facilitate initial information sharing among firms about additives that were materials of concern. The consortium also provided a forum for shared learning about and initial investigation of safer alternatives.

One important difference between the experience of the electronics sector and that of wire and cable producers is that only a subset of wire and cable producers were affected by RoHS, so many of them had no incentive for information sharing. Furthermore, wire and cable producers are so far up the supply chain that many of them were unaware of the changes occurring due to RoHS. The Institute was motivated to start the consortium for the coated wire and cable sector in part as a service to companies that were not receiving information through another route; the consortium provided a means to educate them about policy changes that would affect at least some of them directly over time.

One complicating factor was the concern among formulators that communicating with one another about the ingredients of their products could be viewed as collusion. This concern points to an important role that policy-makers can play in fostering and encouraging this kind of communication. A policy approach can be designed to create space for firms to communicate with one another without concerns about the appearance of collusion.

Due to the differences in incentive structures, the coated wire and cable industry consortium has not reproduced the extensive collaboration that has developed in the electronics manufacturing sector. It has, however, created an environment in which companies have begun to share information about product formulations. This experience indicates that consortium activities can be helpful in addressing toxics problems, even in industries where there are strong pressures against information sharing. At the same time, the combined experience of the electronics and the coated wire and cable industry consortia indicates that regulatory drivers are very important in motivating information sharing; in their absence, little information sharing is likely to occur. Furthermore, in cases in which materials are a key metric for competition, the barriers to communication may be significant.

Opportunities for Policy-Makers: The experiences discussed here point to the importance of designing institutions that can facilitate voluntary information exchange in a way that is consistent with the needs of an individual industry sector. The electronics sector has been very successful in achieving a high level of collaboration. Other sectors may experience different types of competitive pressures that will make this kind of collaboration more difficult, but may nonetheless benefit significantly from strategic initiatives to convene representatives from every link in the supply chain to discuss uses of and alternatives to toxic chemicals.

B. Databases: HPV Challenge Program

Information sharing can be promoted through creation of databases to which companies add voluntarily. The High Production Volume (HPV) Challenge program is an example of such an effort.⁴⁴

Under the program EPA has asked companies to work to fill in basic health and environmental information about HPV chemicals in a database designed and managed by EPA. As this information is filled in, it will be available to any company working with these chemicals, as well as to the EPA and others. The program represents an important step toward filling data gaps about chemicals that are used in large quantities and making basic hazard information on those chemicals available to government authorities, businesses, and the public. However, the program has many weaknesses (described by Denison, Module 1).

The program has not yet reached the targets established by EPA in consultation with industry. All data were supposed to have been submitted by the end of 2005. As of March 2007, of the 2,359 chemicals identified as needing data development, only 39% had final submissions.

In addition to the difficulties meeting agreed upon deadlines, another complication is that the program works from a static list of high production volume chemicals. Since the program began, the production of hundreds of additional chemicals has increased in volume to the point that they qualify as HPV chemicals. For more than half of these chemicals, no screening-level hazard data are publicly available; and a “complete screening-level hazard data set” is publicly available for only about 2% of them. Companies have volunteered to gather data for fewer than half of these chemicals that have newly gained HPV status. A recent review of the program’s results by the advocacy organization Environmental Defense concludes that working from a static list of high-volume chemicals is insufficient to produce the information that is needed in order to make wise decisions about chemical use and production. It is important to gather data on chemicals currently produced at lower volumes as well, since “today’s niche chemical could become tomorrow’s HPV chemical.”⁴⁵

Another weakness of the HPV Challenge program is that the data used to populate the database are not necessarily of high quality. Reviews of the data by Environmental Defense and by EPA have found that for many of the health and environmental data points initially submitted to the database, more testing is needed, either because the data submitted were unreliable or because the information was incomplete.

The experience indicates that it can be useful for a government agency to collaborate with industry on creating a database of chemical information. However, it also shows that the information generated by such a program can be limited in scope and quality, so long as there is no regulatory requirement motivating firms to produce reliable and systematic data. EPA will conduct a quality review of the final data, but if they are found to be inadequate, EPA will not be able to require firms to provide better data.

C. Chemical Management Services

One innovative approach to solving supply chain communication problems, as well as other problems in chemicals management, is to promote the formation of Chemical Management Services (CMS) agreements. In a CMS arrangement, a firm provides an integrated set of services to a customer, rather than simply selling chemicals to the customer. The firm “contracts with a service provider to supply and manage the customer’s chemicals and related services. Under a CMS contract, the provider’s compensation is tied primarily to quantity and quality of services delivered, not chemical volume.”⁴⁶ In the CMS model, a single company is responsible both for identifying and procuring a chemical, and for ensuring that risk is minimized. In this system, a buyer of chemical management services can specify low risk as one of its key parameters. The CMS model removes the incentive for the manufacturer or producer to sell as much as possible of a given chemical regardless of how dangerous it is. It also removes the incentive for a manufacturer or producer to promote a single product for fear of losing market share. A company that positions itself as a provider of chemical services could switch from one chemical to another without losing market share.

One example of successful implementation of the CMS model is available from Raytheon Company. In 1999, Raytheon entered into a CMS agreement with Haas TCM. "The contract covered chemical management for all chemicals and gases, including procurement, inventory, delivery, disposal, and data management. Additionally, the contract included incentives for 'shared savings,' due to reduced chemical use and purchase costs and improved process efficiency. Now in its seventh year of operations, Raytheon's chemical management services program has resulted in elevated performance and savings for the company by reducing chemical usage and streamlining chemical management throughout the chemical lifecycle."⁴⁷

Summary: Options for Policy-Makers: The policy approaches we have described above provide options for achieving several specific goals for information flow. We review these goals below, along with the options for achieving them, and the pros and cons of different means for doing so. Important criteria for judging the value of these options include cost effectiveness; speed of implementation; whether responsibility falls on firms or on the public; demands on government; transparency; and over-all effectiveness in achieving information flow goals.

Goal: Firms provide information on chemical properties: To the extent that firms are able to produce information about the inherent properties of the chemicals they produce, government agencies do not have to undertake this task themselves.

Under the new European chemicals legislation, REACH, manufacturers and suppliers of chemicals must register all chemicals, providing a defined set of information on their health and environmental effects. With REACH as a model and a resource, policy-makers in the U.S. could take steps to introduce a similar requirement at either the federal or the state level.

Requiring firms to submit chemical information to government offers a number of advantages. In particular, by placing the responsibility on chemical suppliers, it avoids placing a large burden on government agencies and increases speed of implementation. It also promotes transparency by ensuring that whatever information is available to a firm, is also available to government, other firms, and (except where limited by CBI provisions) to the public.

A possible disadvantage is that there may be less transparency regarding specific data points. It may be easier for government to guarantee the quality of data collected within government laboratories themselves. This drawback can be addressed to a significant extent through spot checks of data submissions.

The HPV Challenge program is an example of a voluntary approach to achieve the same goal. An advantage to a voluntary approach is that it can be undertaken more rapidly, without an extended period of negotiation. The experience of this program to date suggests that it would be strengthened by the presence of a backstop measure to require data submission if performance is inadequate under the voluntary program.

Data programs such as the HPV Challenge are probably best designed and carried out at the national rather than the state level, but there could conceivably be scope for creating other types of databases at the state level. One potentially interesting example is the case of the Children's and Families' Protection Act in Massachusetts, which requires the state to set up a database to track commercial pesticide sales/use in the state.

At the state level, policy-makers may also be able to use the information generated under REACH to help them in making decisions about chemicals management. Much of this information will be publicly available. Other information will not be available to the public, but there might be opportunities for individual states to enter agreements with the European Chemicals Agency to gain access to this information.

Goal: Firms provide information on chemical use: The 16-year history of Massachusetts' TURA indicates that significant benefits can be achieved by requiring companies to disclose, and pay a fee on, their use of toxic chemicals. One benefit of such a requirement is that it motivates firm-to-firm communication: companies downstream in the supply chain have an incentive to find out what chemicals are contained in the components or ingredients they purchase from suppliers upstream. Another useful aspect of TURA is that the information it provides to the state can be used to help direct resources effectively for research, training and implementation to reduce or eliminate toxics where possible.

From the perspective of cost effectiveness, the TURA program design is quite efficient; firms pay a fee on toxic chemical use, and this fee pays for both data management and direct service to industry by the state. Demands on government are also reasonable: because the program relies largely on training firms in toxics use reduction techniques, firms and independent consultants develop the capacity to promote toxics use reduction themselves. The TURA program successfully achieves significant information sharing from firms to government and the public, as well as from government to firms.

In designing programs to gather chemical use data at the state level, states can adopt best practices regarding trade secret claims, as discussed previously.

Goal: Firms share information with one another on ingredients and alternatives: Structural barriers may impede the flow of information among companies within a supply chain, even when the companies would all benefit from increased information sharing. A government-sponsored program can serve as a network convener, bringing together representatives from each link in the chain, and facilitating collaborative progress in implementing change. As noted in the discussion of two supply chain initiatives in Massachusetts, the existence of a regulatory incentive (in this case European regulations on toxics in electrical and electronic products) can be an important motivator for companies to participate in the program. Advantages of voluntary supply chain collaboratives include the fact that they can facilitate mutually beneficial communication that companies would not necessarily undertake of their own accord. If firms are concerned

about sharing information due to anti-trust regulations, a government sanctioned collaborative can help to allay this concern. Disadvantages of this approach include the perennial problem that firms may lack motivation to participate fully in the absence of a legal requirement to do so. It is likely that these efforts will be more successful in some industries than in others, depending on the competitive structure of the industry and other factors.

Goal: Workers and the public receive ingredient and health effect information: Requiring companies to disclose the chemical ingredients of their products offers state governments a powerful tool. California's Proposition 65 provides one possible model, requiring labeling of any product that contains chemicals listed as causing cancer, reproductive disorders, or other chronic illness. States also could take a step beyond the Proposition 65 requirements, and require that product labels specify which hazardous chemicals are contained in the product. An advantage to disclosure requirements is that they create an incentive for product manufacturers to request information from suppliers upstream. Another advantage is that they provide information to consumers, who can then use their market power to support safer products. Yet another advantage is these provisions can create an incentive for companies to reformulate or redesign products. One possible weakness of Proposition 65 is that it does not require disclosure of specific chemical names.

Warning/labeling requirements such as Proposition 65 place the responsibility on industry to provide information directly to the public. Government fulfills the intermediate step of identifying which chemicals are of sufficient concern that they should be subject to the labeling requirement. The enforcement mechanism for Proposition 65 allows for citizen suits, creating an incentive for citizens and organizations to monitor compliance. This mechanism has the advantage that government does not need to invest significant resources in compliance checks. From the perspective of transparency, Proposition 65 has the advantage of ensuring that anyone who uses a product containing a listed chemical has access to the same baseline of information. Individual consumers, professional users, retailers, and others all have equal access to the information provided on the Proposition 65 label.

Another option for increasing the public availability of information about chemicals in products is to create a publicly accessible registry of products containing chemicals of concern. Some states have done this for individual chemicals, such as mercury. At the international level, new Chinese regulations on toxic chemicals in electronic equipment envision the creation of a comprehensive registry of electronic products containing priority toxics.

Voluntary labeling programs are also an option. Many such programs exist at the state, national, and even international level; labels serve to inform consumers that a given product meets specified environmental criteria.

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- 41 Information in this case study is provided by Gregory Morose of the Toxics Use Reduction Institute.
- 42 Information in this case study is provided by Elizabeth Harriman of the Toxics Use Reduction Institute.
- 43 There are some resin and additive manufacturers in MA. There are many compounders and extruders in MA. In addition to the actors listed in this box, also relevant are: Plus: UL, OEMs, other entities; FPA, national electrical code
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MODULE 3

Assessment and Prioritization of Chemicals: Policy Options for States and the Federal Government

■ JOEL A. TICKNER

How can states best rapidly screen chemicals and rank them for hazards and risks, and how can governments best decide where to focus their risk management efforts and more effectively transition from screening to preventive actions?

Information collection and dissemination serves little purpose if that information is not widely distributed and used for decision-making purposes by a range of actors. Yet with tens of thousands of industrial chemicals in commerce (approximately 2,800 used over one million pounds per year and some 14,000 over 10,000 pounds per year), how can governments decide where to focus their risk management efforts? Can government agencies conduct detailed assessments on every chemical in commerce? How can governments more effectively screen a larger number of chemicals so that preventive actions can be taken more quickly? This policy options module presents regulatory and non-regulatory approaches that government agencies could take to more rapidly screen, evaluate, and make decisions on chemicals. The ultimate goal is that through a more integrated use of accumulated knowledge about chemical hazards, exposures, and risks, agencies and others are more effectively able to rapidly assess, categorize, prioritize, and act on chemicals using prevention measures.

An ideal assessment and prioritization approach should be a thoughtful, science-informed, yet rapid process. Particularly at the state level, technical and financial resources may preclude more detailed risk assessments, which may not be needed to make a determination of whether it is appropriate to undertake some preventive action. Thus, an approach should establish a set of considerations—a process flow to assist agencies in more effectively linking data collection with assessment and voluntary and regulatory prevention activities. It should avoid a “straight-jacket” that keeps agencies from adapting tools and decisions to the particular data and nuances of a chemical. Nonetheless, transparency and consistency in any assessment and prioritization process are critical to ensure its integrity and legitimacy.

Ultimately any evaluation and prioritization process should help agencies get out of the “paralysis by analysis” approach that has characterized chemicals assessment to date (and has been one of the major critiques of chemicals regulation), where few chemicals are reviewed and even fewer acted on. On the positive side, as we will outline below, there are numerous tools, approaches and expertise for more rapid assessment and prioritization of chemicals that already exist and are being used by agencies and companies throughout the world. Clearly, additional tools will be needed. Throughout the process of assessment and prioritization, the following questions should be asked: Are there sufficient data to determine whether there might be a problem or whether concern is low? What are key uncertainties and data gaps and to what extent do they need to be filled in before proceeding? Should risk management techniques be applied and do opportunities occur for prevention that obviate the need for further study?

OBJECTIVES OF AN EXPEDITED APPROACH

Several objectives of such an expedited approach to assessment and prioritization of chemicals include:

- Does the process allow relatively rapid review to facilitate decision-making and remove barriers (for example, lack of knowledge) to decision-making? It would increase the ability of the agency to more effectively screen, assess, and manage larger numbers of chemicals and initiate proactive risk management recommendations at an earlier point in decision-making.
- Does it avoid unnecessary, expensive, and protracted evaluations and risk assessments so that existing resources can be used more efficiently to identify chemicals needing risk management actions (voluntary before regulatory thresholds have been met or regulatory measures), those needing further study, and those that are frequently safer that do not need such actions for the time being?
- Does it encourage broader consideration of potentially safer or greener chemicals and design at the design stage of chemicals and for existing chemicals when concerns are raised? It would integrate consideration of available alternatives in the discussion of chemical risk and appropriate actions.
- Does it promote implementation of safer chemicals in a timely and thoughtful manner—supporting innovation?
- Does it focus on how much information is needed to make informed decisions rather than on “perfect” knowledge?

Agencies generally follow few set structures for chemicals assessment and prioritization. However, in some cases agencies may create decision-rules for steps that must be taken before regulation begins (for example, the new industrial chemicals screening process at the U.S. Environmental Protection Agency (EPA) outlines a process for reviewing chemicals and describes thresholds for undertaking actions). In other cases, practice, such as the National Academy of Sciences four-step approach to risk assessment, defines the process of decision-making.

Assessment and prioritization is not normally a linear process and is typically iterative in nature (for example, a chemical may be re-screened as new data are submitted). Often, prioritization accompanies screening (or may even precede screening, such as determinations to focus on persistent chemicals) or may occur after some initial evaluation. Sometimes assessment is integrally linked to screening. Thus, the examples presented below of options often transcend several steps of the screening, prioritization, assessment, and decision-making process, though they may be highlighted in only one of these steps. The extent and order to which each of these steps is followed also depends on whether the decision is a regulatory one (in which certain thresholds for action must be met) or a voluntary one.

In this module, we present options for more rapid screening, assessment/prioritization, and decision-making. Clearly they overlap in that, when dealing with a chemical recognized as a high concern at the screening stage, an agency may forego detailed assessment and move straight to risk management. We conclude with some general thoughts on more effective assessment and prioritization at the state level.

CHEMICAL-BY-CHEMICAL RISK ASSESSMENT SLOWS DECISION-MAKING

Current approaches to chemicals policy involve requirements for extensive data and chemical-by-chemical risk assessment before preventive action can be taken. In Module 1, Denison notes the paucity of data available on chemical toxicity and exposure that hinders risk assessment activities. Unfortunately, the lack of data on chemicals and uncertainty about their human or ecological health risks often are misconstrued as evidence of safety. In other words, as long as data are missing or there is uncertainty as to a substance's impacts, no action is taken.

Under the Toxic Substances Control Act (TSCA), before EPA undertakes restrictive risk management measures, it must demonstrate an unreasonable risk involving two steps: 1) First, EPA must demonstrate that the risk is unreasonable. EPA is required to undertake extensive risk assessment activities (with adequate hazard and exposure data which means additional tests and data collection usually are required before even undertaking a risk assessment) to demonstrate such a risk. Risk assessments can take several years to complete and may cost millions of dollars for each chemical. While such assessments are being completed, the default decision is implicitly that the risk is not unreasonable and the exposure continues; 2) Once EPA makes a determination of significant risk, it must then demonstrate that the risk is "unreasonable," which under TSCA means that the benefits of regulation must outweigh the costs and that the action taken by the agency is the least invasive to meet a particular risk reduction goal.

The Current Limitations

Current risk assessment-based approaches for more efficient chemicals assessment and action have several limitations¹:

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- **Risk assessments generally are used for quantifying and analyzing** problems rather than trying to solve or prevent them. Quantitative risk assessments generally are used to set “safe” levels of exposure that correspond to an agency’s pre-defined “acceptable” level of risk, and assume that a population or individual has a certain assimilative capacity. This situation avoids discussion of whether certain characteristics of chemicals (for example, persistence and bioaccumulation) or hazards (such as ability to cause cancer or reproductive impairment) should be avoided entirely.
 - **Risk assessments do not consider whether there may be alternatives** that would reduce or eliminate the risk in the first place. In this respect, a focus on detailed risk assessment before actions take place can inhibit innovation in safer chemicals and materials.
 - **Risk assessments often limit consideration** of uncertainties, multiple exposures, cumulative effects, sensitive sub-populations, and/or end-points other than cancer.
 - **Risk assessments are based on numerous assumptions** about exposures, human behavior, chemical effects, and chemical fate that may or may not be realistic or may miss important considerations.
 - **Risk assessments can be expensive and time consuming** and often tie up limited resources. Given the contentious nature of such analyses, debates over nuances (for example, specific models or uncertainties) can stave off preventive actions for long periods of time.

For example, it took the Occupational Safety and Health Administration nearly a decade to finalize a standard for methylene chloride. Many of those years of debate — over a chemical known to be problematic — were focused on minutiae about how the chemical was transported through the human body and caused its toxic effects. While these debates occurred, workers continued to be exposed to what has now been deemed a potential carcinogen. This approach to chemicals policy is not only inefficient, it has been harmful to health and ecosystems. Indeed, if scientific research had been focused on analyzing alternatives to methylene chloride in various industrial operations while *simultaneously* exploring the substance’s mechanism of action, debates over toxicologic mechanism might have been avoided and workers would have been better protected sooner because debates over toxicologic mechanism would not have been the only focus of action.²

Hazard Data, Exposure Data, or Both?

Debates in chemicals policy efforts are addressing whether decisions to prioritize or act on chemicals should be made on the basis of only hazard data or whether exposure or risk data also should be considered. Hazard represents an inherent characteristic of a substance — for example, perchloroethylene will always be inherently carcinogenic. Whether a person will get cancer depends on exposure. However, exposures often are hard to measure and there are significant uncertainties concerning how much exposure (when combined with other exposures and stressors) might lead to cancer. Further, one must consider the lifecycle of a substance when thinking about exposure potential. For example, just because perchlorethylene is used

in a closed vessel does not mean that it will not be released into the environment at the end of its life (that is, in disposal). Thus, reducing the inherent hazardousness of chemicals should be an important goal of chemicals policy efforts (indeed, the field of green chemistry is based on reducing the hazards of chemicals, not exposure, and the field of pollution prevention focuses on reducing waste and chemical use in facilities on the basis of the inherent toxicity of materials not their risk).

Similarly, exposure data are very important to understanding high risk populations and chemicals of concern due to high exposure (a lower toxicity chemical may be of higher concern by nature of its types of exposure). Exposure information thus can help identify potential risk trade-offs, for example, increased exposures to workers or a new potential use of a chemical that could increase hazardous exposures. Exposure data also may be helpful in considering how a chemical behaves in the environment. For example, a purely hazard-based system may not identify the problems of mercury in the environment (formation of methyl mercury). That said, exposure assessment is expensive and resource intensive so surrogates of exposure, such as production volume, use quantity, or use category/type can be very helpful in efforts to identify problem chemicals and identify opportunities for prevention. In this respect, particular chemicals and uses of chemicals may be prioritized more rapidly for preventive actions.

This discussion is not suggesting that there is no place for risk assessment in chemicals policy efforts. Rapid risk assessment processes (quantitative and qualitative) can be very useful in prioritizing chemicals of concern, in comparing alternatives, or in determining clean-up levels for contamination. Several examples of rapid risk assessment processes are described below. However, it is important that policy structures are designed so that decision-making is not contingent on chemical-by-chemical risk assessments and that availability of safer alternatives becomes as much a consideration in the decision-making process as the chemicals' hazard/risk.

CHEMICAL SCREENING – EXAMPLES AND OPTIONS

The data generation process has been discussed in a separate module (Denison, Module 1). Screening is generally a first-pass examination of hazard data. Screening—like in medical testing—should focus on avoiding false negatives (making a determination of low or no hazard when hazard does indeed exist). Since it tends to occur early in the decision-making process, screening-level data tend to be less complete, but the process of review tends to be more rapid in nature. However, screening can support decisions to use or not use a particular chemical (on the basis of some identified hazard) and can serve to identify negative attributes in a chemical. Screening should be iterative and reoccur as new data are collected.

Some laws require chemical data to be provided to government agencies, for example, on studies that can identify particular hazards or toxicity; on chemical use or exposure; or chemical properties. Sometimes data are collected because a concern has been raised about a substance

in the scientific literature or by agencies or communities or a scientific body, such as the U.S. Interagency Testing Committee, has identified a chemical of concern because it is being found in the environment or in human tissues.³ In the case of the EPA's High Production Volume (HPV) Challenge Program⁴ and the Organization for Economic Co-operation and Development (OECD) equivalent⁵, data are collected as the result of pressure placed on industry to assume voluntary responsibility. Finally, in some cases, responsibility lies with industry to submit chemical data. This is the case for most countries' new chemicals programs and for information that indicates new hazard or risk knowledge about the chemical. In Europe, with the implementation of the Registration, Evaluation and Authorization of Chemicals (REACH) legislation, there will be systematic data collection requirements for all chemicals in commerce over one metric ton per year.

Once data are collected, agencies can then screen them to examine quality and in some cases determine whether a substance is of low concern and thus in need of no more evaluation, of higher concern and in need of further testing, or of unknown concern and in need of further testing. Screening often involves only review of the inherent toxicity (hazard) of a substance but it also may include consideration of potential uses and exposures.

After initial screening of data is completed, under current policies a likely outcome is collection of further data to fill in gaps, understand exposures, uses, or hazards and obtain more information for decision-making. Such requirements often happen in the context of applying laws such as TSCA, under which an agency will request particular studies to better understand the risks of a particular chemical based on initial data the agency has received. More detailed studies tend to include sub-chronic toxicity and exposure scenarios. At the state level, such studies often are completed in response to exposures or impacts at the local level, for example, perchlorate in drinking water supplies or more recently body-burden testing. Such studies generally support media-based (for instance, water, air) decision-making at the state level where states generally have strong regulatory capacities. They can often slow down decision-making processes while data are collected and may tax the financial and technical resources of agencies.

Screening processes can be important in understanding the hazards of a particular substance. Screening can serve as the first step in prioritizing (or even accompany prioritization) and can lead to risk management measures for chemicals of concern, if clear criteria are pre-defined (such as persistence and bioaccumulation). In general, initial screening can determine whether there is a potential hazard that merits further study or action, *not whether there is no hazard*. Initial screening processes, even those that include test data, should not lead to determinations of safety though they could lead to a determination of lower priority for further action (see Module 1, Denison).

Several options for chemical screening could be instructive in examining regulatory and non-regulatory options for action. They include: 1) government provides industry the tools to undertake regulatory or voluntary screening with government review; 2) government requires industry to submit information/undertake screening; 3) government agencies undertake screening on the basis of existing data.

OPTION 1: Provide industry with the tools to undertake regulatory or voluntary screening with agency review. Under such an approach, government agencies would provide industry with tools to screen chemical toxicity and potential exposure to their chemicals. Industry would not be required to develop new test data but use available test data and surrogate sources, such as Structure Activity Relationships, to develop such a submission. Companies would complete the data analysis and submit it to a government authority for review and potential further action. The model for this approach would be 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. The program improves the quality of the pre-manufacture notifications firms send to EPA for new chemicals and facilitates EPA's rapid assessment (see example below under assessment).

There are two potential options for such an approach: 1) voluntarily ask all chemical manufacturers in a state or user sectors to submit such a "dossier" to the appropriate agency by a particular date; or 2) require such submissions. In either case, it would make sense for such "dossiers" to be submitted for both "new" and "existing" chemicals manufactured or imported into the state. A benefit of a voluntary approach would be the relatively low cost of implementation (simply technical support and outreach to industry to provide access to and training on the tools and requirements as well as agency review). This option could be limited to simply the industry submission with very little agency review (simply a check for completeness) or include a more detailed rapid agency assessment (screening and assessment together). A limitation would be participation in the program. A positive aspect of a regulatory requirement would be an ability to ensure a more comprehensive picture of chemical toxicity and possibly better access to use/production data in a single location. Such a dossier can go beyond the current requirements for new chemical submissions under TSCA and include information on chemical use and exposure.

Example of Option 1: EPA Sustainable Futures Program.⁶

Under TSCA, manufacturers and importers of new chemicals must submit a pre-manufacture notification (PMN) to the EPA 90 days before initial manufacture. The PMN must include data about chemical identity and potential uses but in most cases no new test data are required. As such, EPA relies extensively on structure activity relationships in the chemical review process. Given the lack of test requirements, EPA has developed a series of tools to assist in developing usable data for this process, including exposure assessment, fate and transport; aquatic toxicity and carcinogenicity prediction; and prediction of persistence, bioaccumulation and toxicity. EPA understands that the most effective time to promote safer chemistry is in the design stage, particularly since EPA's authorities for regulating chemicals once on the market are limited. Through the Sustainable Futures Program, EPA trains industry chemists in the use of these design and predictive tools, in chemical toxicity and process design, and how to reduce chemical impacts at the design stage. EPA has trained hundreds of industry scientists in these tools, often in conjunction with industry and academic partners.

OPTION 2: Require industry to submit information/undertake screening. Under this approach, manufacturers and importers of chemicals would be required to submit a chemical screening dossier consisting of actual test data (and surrogate data where it can be justified). The chemical dossier would include information on chemical characteristics, uses, and exposures and a screening-level hazard/risk assessment as well as risk management recommendations for safe use. In such a case, chemicals could be grouped into categories for submission. A model for this is the REACH registration dossier (see below).

A strength of this option is the burden on manufacturers to develop and provide the data. However, government agencies would have to develop data management systems to compile and use the data. Such an approach would be costly to industry and likely would require significant government oversight resources.

Example of Option 2: The REACH Registration process.⁷

Under the European Union's REACH legislation, all chemicals manufactured or imported over one ton per year per manufacturer or importer will need to be registered. The registration requirements (including testing) will depend on the tonnage produced or imported. In general, testing can be replaced with information derived from alternative approaches if the approach is validated. All chemicals will have a base set of data and those chemicals manufactured or imported over ten tons per year will have a Chemical Safety Report, which in some cases must include a qualitative risk assessment for each use of that chemical. The burden is on the manufacturer/importer to provide this information. When registrations are submitted to the new European Chemicals Agency, they will generally not be screened other than a quick review for completeness. Such dossiers will be reviewed for quality during the evaluation phase (see below).

OPTION 3: Government undertakes screening on the basis of existing data. In this case, government agencies would screen a defined group of chemicals (for example, all chemicals used over a certain tonnage threshold, all chemicals on a substance registry, all Toxics Release Inventory (TRI) chemicals used in a state) to assess potential hazards/risks, develop hazard classifications, and identify chemicals that require additional data or potential action. Such screening processes are done on the basis of data already provided to an agency (for example, high production volume chemicals data) or structure activity relationships. They tend to be rapid assessments to identify additional requirements or actions. They can be combined with a voluntary data "call-in" to industry to provide data for the screening process.

A positive aspect of such approaches is that they are relatively inexpensive (relying on current data) and are undertaken by the agency without having to go through a regulatory negotiation process to collect data (though given limited agency budgets, legislative mandates may be helpful to stimulate such activities) and can be done in a relatively rapid manner to facilitate

decision-making. A negative is that it requires agency technical and financial resources to undertake the assessment. Further, a data-based screening approach requires data to be available which would first require some type of data submission process. Two examples of such assessment processes — one using data submitted to an agency and one using SAR data — are presented below.

Example of Option 3: Screening Process for EPA's HPV program.⁸

A concern raised in the early years of EPA's voluntary HPV Challenge Program was how the agency would actually use the data to make decisions. A federal advisory committee, the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), developed a two-tiered screening program for HPV chemicals — that has since been adopted by EPA. Tier I screening is nearing completion and EPA completed 50 Tier II screenings as of the end of 2007:

Tier I. Tier I is an automated process whereby key elements of a submitted HPV data set are screened against predetermined criteria (hazard criteria from the Globally Harmonized System of Classification and Labeling — GHS) to establish a logical order in which the Office of Pollution Prevention and Toxics should review the chemicals or categories of chemicals. The industry submissions were taken at face value with no review of quality or completeness at this tier. A set of three review groups (decreasing priority) was established for Tier II review (with up to one-third of submissions in the highest priority group). NPPTAC notes that the results of Tier I review do not provide a final judgment of hazard or risks, if any, of a chemical/category.

Tier II (to be completed over a two- to four-year period for all chemicals). Under Tier II, EPA would conduct a more in-depth review of the data in the Challenge Program submissions for quality and completeness; develop a screening-level hazard assessment based on the HPV screening level data (SIDS) and other hazard data provided by the sponsors; and inform the sponsors and the public of its findings. NPPTAC notes that Tier II is not an assessment of the exposure potential or risks of a chemical. The key outputs of a Tier II review are a determination as to the adequacy of the submitted data and a screening-level hazard characterization that is posted in the public HPV Information Service database. A Tier II review could lead to the following next steps: 1) gathering additional information on uses (for example, by use function, category, release potential, or benefit) and exposure (to humans and/or the environment); 2) gathering additional information on hazards to support a more in-depth characterizations; 3) evaluating existing federal and state regulatory controls (for example, occupational exposure limits); 4) providing information referrals or recommendations for actions to other EPA programs or other federal or state agencies; 5) initiating a risk assessment led by EPA, another agency, industry, and so on; or 6) deciding after closer examination that no further action is needed at this time.

Example of Option 3 – Danish EPA Classification.⁹

In 2000, the Danish government issued an advisory list for the classification of dangerous substances. Through the use of quantitative structure activity relationships, the Danish government examined approximately 46,000 substances and classified 20,624 according to acute lethal toxicity, sensitization, mutagenicity, carcinogenicity, and aquatic toxicity (European Union chemical classifications). This rapid screening and classification process has been important for the country to more effectively use resources for targeting chemicals of concern. The government has already prioritized some chemicals — such as PBTs — as being of higher concern.

OVERVIEW OF OPTIONS FOR CHEMICAL SCREENING

This table summarizes the three options for chemical screening outlined above for speed, cost, resource needs, transparency, and performance. L=low; M=medium; H=high

	Option 1 – Provide tools to industry for voluntary screening	Option 2 – Require industry to submit data/undertake screening	Option 3 – Government screening on the basis of existing data
Speed of implementation	M	L	H
Cost			
Industry	M	H	L
Government	M	L	M
Technical/human resource needs			
Government	M/H	M	M/H
Industry	M/H	M/H	L
Public access to information/transparency	L/M	M	M
Performance – ability to expedite decisions and lead to implementation of safer chemicals and uses	M	L	H

Chemical Screening: Key Considerations

Any chemical screening process should involve several key considerations:

- **The chemical “universe” subject to screening.** Is it all chemicals manufactured or imported into the state, all chemicals used in the state, chemicals released in the state, higher volume chemicals, chemicals in a particular sector, and so forth? In this context, should data be requested/required for only chemical manufacturers and importers, high volume users, or all entities that sell chemical products? The challenge of requirements for entities that sell chemical products is the establishment of some type of chemicals registry to track use. Clearly, the more chemicals involved, the more burdensome the process will be.

- ***To what extent chemical use and exposure information should be considered at this phase and how.*** Screening processes are generally hazard-based. However, information on the type of use (also called use category) can be very helpful at this stage in identifying potential actions and prioritization. For example, a substance for which screening indicates that it can be persistent or bioaccumulative and is used in an open consumer use could be considered of higher concern (see below).
- ***How lack of data should be treated in screening processes.*** When data are not available, the lack of data (which may include the inability to reliably estimate the hazards of a chemical on the basis of structure-activity relationship models) should itself be construed as evidence of potential concern about that chemical. This fact provides an incentive for companies to rapidly generate data for screening processes (particularly in voluntary processes). In government-initiated screening processes, agencies should use the most conservative, worst-case assumptions regarding potential toxicity of a substance in their screening processes. It would be akin to the idea of sensitivity in a disease screening process where it is preferable to not miss a disease (and overpredict disease) than to miss one. Nonetheless, alternative substances may not have the same extent of testing/data as older substances of concern. More years of testing should not be construed as greater evidence of safety. While an alternative substance may not have as much test data as the substance it may be replacing, it may be enough to indicate that it is safer. **In general, determining comparative safety of two substances does not require as much data as determining the safety of a single option.**
- ***How knowledge can be updated in an efficient manner.*** Screening should be viewed as a dynamic process. Mechanisms should be in place to update screening-level knowledge (as knowledge about a particular chemical class or structure improves) and to require submission by chemical producers and users of any information indicating a hazard or exposure concern.
- ***Agency capacity to undertake screening or compile data.*** Chemical screening capacity within agencies differs from state to state. Some states, such as California, have extensive resources for data collection and screening, while smaller states may not have the resources to undertake extensive screening processes (or even data collection). As such, options will differ from state to state. States may be able to combine resources to initiate a regional screening process. Or states could require industry to undertake the screening process.
- ***Whether to undertake a regulatory or a voluntary approach to screening.*** The type of approach will depend on the purpose of the screening process. For a registration type process, such as that under REACH, a mandatory data generation and collection approach would be reasonable. If an agency is attempting to prioritize chemicals of concern, a voluntary government-initiated approach may be the most appropriate.

ASSESSMENT AND PRIORITIZATION PROCESSES—EXAMPLES AND OPTIONS¹⁰

When initial data are collected and screened, a next step under many current policy systems is to evaluate chemicals to determine which require further study or action. Assessment can often be a very resource- and time-consuming process—particularly if detailed risk assessments are conducted. But assessments can be streamlined, for example, examining the inherent hazards of a substance (is it a carcinogen?) or exposures (what are potential exposures to consumers from this substance?) or risk (what is the likelihood that someone might be harmed from this exposure?). More rapid decision-making on a greater number of chemicals will require the development of more rapid assessment tools. Often, hazard assessments are completed instead of or before more extensive risk assessments — such as the cases of the OECD’s Screening Information Data Sets (SIDS) program, U.S. EPA’s HPV Challenge. By themselves, they can be the basis for actions, such as listing a chemical on the Toxics Release Inventory.

With a large number of chemicals in commerce, it would be difficult for any agency to undertake detailed assessments on each of them. As such, agencies will have to determine which chemicals are more and less problematic. Assessment efforts (and often screening-level efforts) frequently include prioritization processes (or may even be preceded by them). Prioritization (as well as a similar process called Categorization, whereby a list of chemicals is “categorized” as to its hazard or risk characteristics) is the process of determining which chemicals are of higher and which of lower concern. Prioritization is a way for agencies with limited resources to determine where to most effectively target resources. It is the process of sorting or ranking chemicals (like taking a sieve) as a result of applying a set of criteria or methodology. Prioritization efforts often are explicitly linked to decision-making processes (for example, carcinogens should not be used in workplaces). These processes are examined in the next section.

Prioritization processes can be undertaken on the basis of hazard (inherent toxicity) or qualitative risk (for example, chemicals in consumer products). A group of chemicals can be prioritized based on inherent hazards (for example, persistence or bioaccumulation or carcinogenicity) or as the result of a screening process that identifies hazard criteria for action. For example, the state of Washington has prioritized Persistent Bioaccumulative and Toxic (PBT) chemicals for regulatory action.¹¹ The Swedish Sunsetting process prioritized persistence and bioaccumulation along with the goal of achieving a non-toxic environment within one generation.¹² REACH prioritizes certain types of substances, such as persistent and bioaccumulative toxics. The Canadian Environmental Protection Act (CEPA99) required the government to undertake its categorization process with clear concern for persistence and bioaccumulation.

Various models for rapid assessment and prioritization processes could be used to support sustainable decisions on chemicals management. They include:

OPTION 1: Government agency undertakes rapid or detailed substance assessments.

Under this option, a government agency would undertake a substance-by-substance (or chemical class) based assessment of chemical toxicity and/or risk to determine whether further actions (including study) are needed. Such an assessment can be done on the basis of data collected by the agency — from previously conducted studies — or data provided by industry (voluntarily or required, such as under the REACH process). They also can be conducted on the basis of structure activity relationships, such as the assessment process for new chemicals under TSCA. These assessments also can be based on a specific endpoint — carcinogenicity and reproductive toxicity — as well.

A positive aspect of this type of analysis is that it provides a detailed assessment of hazard or risk of a chemical which can then be used to support more aggressive policy measures — such as restriction of a chemical class or a mandate for clean-up activities. The technical, data, and financial requirements to undertake such assessments are negative aspects.

Example of Option 1: Detailed chemical evaluation under REACH.¹³

Under the REACH Registration phase, the European Chemicals Agency will receive a registration dossier for all chemicals manufactured/used over one metric ton per year. Submitters will be responsible for undertaking a chemical safety report for all uses in some cases as well as submitting a chemical classification. The European Union has in essence prioritized the data collection process for certain types of chemicals—those produced in high volumes and those that on the basis of their initial hazard categorization are persistent, bioaccumulative and toxic, or are carcinogens, mutagens, or reproductive toxicants. These chemicals (including five percent of all registrations) will become candidates to undergo a process called Evaluation, whereby European Member States have the authority to review the quality of the data (including whether further study is needed), and evaluate the assessment done by the registrant and the adequacy of the risk management measures they and their downstream users are employing to mitigate risk. For chemicals actually selected for Evaluation (estimated to be about 50 per year), the REACH legislation includes timelines for completion of the evaluation process so that decisions can be made.

Example of Option 1: Rapid Carcinogenicity Assessment under the California Safe Drinking Water and Toxic Enforcement Act Risk Screening Process.¹⁴

Under the California Safe Drinking Water and Toxic Enforcement Act (of Proposition 65), the California Environmental Protection Agency (CEPA) was required to conduct health risk assessments for the 396 list carcinogens and reproductive toxicants. By 1991 conventional risk assessments were prepared for only 77 of those chemicals. The need to have risk figures to understand possible public health implications of these chemicals led to the development of rapid risk assessment procedures using the Expedited Linearized Multistage Model Default procedures. The methodology uses estimations of human cancer potencies derived from potency values in animals, multiplied by an appropriate interspecies scaling factor. The advantage in the use of

LMS procedure is its similarity to conventional risk assessment, using default assumptions in data selection, but the process is more rapid since it is based on available information. The comparison between the 77 chemicals examined in conventional assessment and another 125 chemicals using the LMS procedure, makes more than 200 potency estimates in less than a year.

Example of Option 1: EPA rapid assessment under the TSCA New Chemicals Program.¹⁵

When industry submits a PMN under TSCA, EPA must review the submission to determine if the chemical may present an unreasonable risk or significant exposure within a 90-day period. The EPA new chemicals review has a well-defined process that has been described elsewhere but generally includes an analysis of chemical hazard, potential exposures (also using modeling data), and chemical risk. EPA's rapid review of the data includes a multi-disciplinary group of agency scientists who meet to discuss various aspects of the data submitted and generated by the agency to determine whether regulatory action or voluntary negotiation (including recommendations for testing or dropping a chemical from review) are needed. EPA has a database of more than 30,000 chemicals reviewed and also has developed a set of "chemical categories" which the agency defines as chemicals that are similar structurally and have a consistent set of hazards; if a new chemical falls into one of these categories, that is a basis for EPA to require additional data for safety determinations or to impose risk management conditions. This list of chemical categories in part helps to screen for chemicals that might be of concern to the agency and industry submitters are notified of additional requirements for chemicals in these categories (or to avoid certain types of chemistries). Through this process, EPA reviews more than 1,000 chemical submissions per year and regularly corresponds with industry submitters of data to discuss concerns.

OPTION 2: Government agency undertakes rapid classification/prioritization process.

This approach is similar to the rapid screening process outlined above but goes further to classify chemicals for priority action on the basis of some pre-defined criteria—hazard, exposure, risk, and so on. This approach actually may include less detailed data evaluation than the previous option and hence the two might be combined or prioritization may precede assessment. The purpose of the activities is generally to channel resources into chemicals of higher concern and provide signals to manufacturers and users of chemicals about substances that will be of greater concern to an agency. Analyses can be done on the basis of the intrinsic hazard of a chemical or qualitative assessment of risk or some type of quantitative estimation algorithm.

A strength of the approach is that there is little or no industry burden for an agency to undertake such an analysis and it can provide important signals to manufacturers and users of chemicals. A weakness is that the approaches do require expertise and resources which may have to be allocated by a state government. Such a process can be required in law, have timelines for completion and financial resource commitments, and have requirements for an agency to seek additional data where needed to complete the prioritization.

Example of Option 2: Rapid Screening through the Canadian Domestic Substances List (DSL) Classification.¹⁶

Created in 1991, the Canadian DSL is a list of substances that were “in commerce” in Canada between 1984 and 1986. The CEPA99 required that the Canadian government undertake a categorization of chemicals used, manufactured, or imported into Canada (approximately 23,000 substances). Categorization was defined as an efficient but sound prioritization process for further screening and action on DSL chemicals that may present greatest potential for exposure or are persistent or bioaccumulative and inherently toxic. The categorization process consisted of a human health and ecological health evaluation on inherent toxicity (conducted by Environment Canada and Health Canada) as well as an assessment of exposure potential (exposure and persistence and bioaccumulation). Through this categorization process about 4,300 chemicals have been identified as needing further assessment/action and about 500 chemicals have been listed as high priorities for further assessment/action. The DSL categorization process has been integrated into the new Canadian Chemicals Management Plan.

Example of Option 2: Quantitative prioritization algorithm — EPA Toxics Release Inventory (TRI) Prioritization Effort.¹⁷

The University of Tennessee Center for Clean Products and Clean Technologies developed a prioritization method for the EPA that consisted of relative risk ranking and scoring for a combination of health and environmental toxic effects of TRI chemicals. Toxicity data were collected from the Hazardous Substances Database and by using Structure Activity Relationship analysis, specifically for estimating physicochemical properties and environmental effects. The method used a two-tiered approach to avoid false negatives (screening tier) and false positives (confirmation tier). The preliminary Screening Tier identified chemicals released in high quantities in the TRI and high-volume pesticides (158 chemicals). Weights were given to values for the environmental and human health categories. Exposure potential was estimated on the basis of persistence and bioaccumulation parameters. The algorithm for the hazard ranking was:

Total Hazard Value = (Human Health Effects + Environmental Effects) x Exposure Potential.

Following the screening tier, used to identify priorities and potential alternatives, the confirmation tier was used to confirm the highest priority chemicals.

Example of Option 2: Qualitative risk-based prioritization scheme — Chemical Use Categorization Process.

Over the years, several use category-based prioritization systems have been proposed. Such processes help to prioritize and group chemicals not only on the basis of hazard but also broadly on their particular uses. Use categories or clusters can be defined as the general group of use for a particular substance, for example, open consumer uses; or adhesives; or solvents. In 1994, Warren Muir proposed a use-based categorization system for chemicals noting that the uses of toxic chemicals in specific settings allow harmful effects to occur. His proposal was that produc-

ers and users of chemicals should be provided with guidance on reasonable uses of chemicals and that this guidance should form the basis of EPA's prioritization of chemicals for prevention activities. This guidance would provide general guidelines for when specific chemicals can be problematic — that is, a reproductive toxicant or one that is persistent and bioaccumulative in a product use and should be subjected to pollution prevention actions.

A generic scheme outlined by Muir for prioritization of chemical uses is as follows. Under this scheme, a substance would have a higher priority based on its intrinsic hazard combined with its use and how it is used (exposure potential):¹⁸

	Closed System	Controlled Use	Dispersive Use	Direct Exposure
1. Research Chemical				
2. Raw Material				
3. Reagent				
4. Product Ingredient				
5. Essential Processing Agent				
6. Non-specific Processing Agent				
7. Waste by-product				
8. Indoor Consumer Use				
9. Outdoor Consumer Use				

OPTION 3: Provide tools to industry to conduct substance assessments. Government agencies could provide tools for industry to voluntarily complete their own substance assessments and prioritizations. Assessments also could be mandatory (see REACH registration process above). In this option, tools and criteria would be provided to companies to develop assessments that then could be kept within a company (or possibly be submitted confidentially to an agency). For example, companies could be provided with training on the EPA's new chemicals assessment tools, such as the PBT profiler, to undertake PBT assessments of chemicals manufactured and used. Or companies could be trained on using the GHS, to undertake the full GHS, despite sections which are not adopted at the federal level in the U.S. The benefit of this approach is for firms to understand the potential risks of the chemicals they use and possible trade-offs between chemical choices. Its use would internalize thinking about chemical toxicity and safety at the design stage of chemicals and products.

Example of Option 3: Massachusetts Toxics Use Reduction Institute (TURI) Prioritization and Assessment Processes.¹⁹

TURI provides research and educational support to Massachusetts businesses to improve toxics use reduction planning and implementation efforts. TURI has developed a number of tools to assist firms and government agencies in decision-making about chemicals. One such tool is the Pollution Prevention Options Analysis Tool (P2OaSys). P2OaSys is a comparative chemicals hazard assessment tool to help companies examine a broad range of acute, chronic, physical, environmental, and chemical property hazards in comparing toxics use reduction options. P2OaSys uses existing data on chemicals to identify worst-case potential impacts from current and alternative options and provides a disaggregated comparison of the health, safety, and environmental tradeoffs between alternatives.

OPTIONS FOR CHEMICALS ASSESSMENT AND PRIORITIZATION

This table summarizes the three options for chemicals assessment and prioritization outlined above with regard to speed, cost, resource needs, transparency, and performance. L=low; M=medium; H=high

	Option 1 – Government agency undertakes rapid or detailed substance assessments	Option 2 - Agency undertakes rapid classification/prioritization process	Option 3 – Provide tools to industry to conduct substance assessments
Speed of implementation	L/M	M	M
Cost			
Industry	L	L	M
Government	M/H	M	L/M
Technical/human resource needs			
Government	M/H	M	M
Industry	L	L	H
Public access to information/transparency	M	M	L
Performance – ability to expedite decisions and lead to implementation of safer chemicals and uses	L/M	M/H	M

A number of considerations must be addressed in determining options for assessment and prioritization. Clearly, like screening, the extent of assessment and prioritization will

depend on the resources available in a particular state. The considerations include:

- **The level of detail of assessments.** The level will depend on the context of the decisions to be made. For a clean-up decision where costly clean-ups may be required, more detailed risk assessments (with actual test data) may be warranted so as to ensure that resources are not overly taxed. Similarly, for regulatory decisions to restrict a particularly important chemical in commerce with critical uses that may not have good substitutes, more detailed assessments may be needed. For a decision whether to list a chemical on a list of chemicals of concern or to prioritize it for voluntary action, less detail (for example data based on SARs) will likely be needed.
- **Grouping of chemicals in assessment processes.** Given the sheer number of chemicals to evaluate, efforts that group structurally similar chemicals or chemicals within a category (brominated fire retardants) will be more efficient. They also will be more controversial since some may argue that chemicals are different toxicologically.
- **The extent to which use and exposure are considered at this phase and how.** States will have to decide if hazard alone is sufficient to determine whether a chemical should be prioritized for action. Exposure assessments are generally harder to conduct due to the sheer absence of data on exposure (and of chemical uses through supply chains) which could lead to an underestimation of potential exposure and ignore the intrinsic toxicity of a substance that could pose problems at any stage in a product lifecycle. Given the challenges of assessing exposure, it may be useful to find surrogates for exposure — open consumer use and so forth — so as to prioritize chemicals. Use and exposure can effectively be used at this stage to prioritize certain chemicals that may have very high use or high exposure (for example, in body burden), exposures during sensitive developmental phases (children or the elderly) or exposures to sensitive sub-populations, such as in contaminated communities. It may be useful to keep such information separated and not combined (in a risk assessment) to identify a greater range of opportunities for prevention.
- **Determining which chemicals/uses are the highest priority.** Prioritization at this stage will require that criteria be developed for what makes a substance a lower or higher priority. What inherent hazard characteristics (persistence, carcinogenicity, and so forth) and what exposure or use characteristics lead one to prioritize a particular chemical. Agencies may provide guidance to chemical manufacturers and users. Agencies would have to determine a set of hazard, physiochemical property or exposure triggers that lead to higher or lower concern (for example, persistence and bioaccumulation or reproductive toxicity, neurotoxicity, developmental toxicity or carcinogenicity, or high/consumer exposure). Categories could include high concern, medium concern, or lower concern. There is some debate about whether such processes are effective in identifying chemicals as “safer” or “preferable” chemicals, though some criteria for greener chemicals would be useful. Sometimes such decisions can be made on the basis of available science, but significant judgment is required to decide what types of chemicals are more problematic than others.
- **Determining whether further analysis/assessment is needed.** In some cases, it may be necessary to undertake more detailed assessments — for example, in clean-up decisions

or where a chemical is widely used in industrial sectors—before moving to a decision stage (though more study is an action decision). In such cases, it may be necessary to develop priorities and timelines for data collection for further assessment — toxicity (mechanisms), uses, supply chain data, emissions, sensitive subpopulations (for example, cumulative exposures), and so forth. Agencies will have to decide whether important data gaps exist that must be addressed before taking action; whether risk management measures are needed or the assessment process can stop — that is, the chemical is reasonably safe or greener and no further actions are needed; whether there is a need for more detailed risk assessment and what are the trade-offs between conducting such assessments and continued exposure; and whether additional on-going data requirements are needed — for instance, data requirements as production levels rise.

- ***Who should complete prioritization processes?*** Given the lack of guidance from some governments, many firms have begun their own chemical prioritization processes, often on the basis of regulatory demands or market pressures. In general, it makes most sense for governments to provide guidance on chemicals of higher or lower concern and to identify classes or groupings of chemicals of concern.

DECISION-MAKING BASED ON SCREENING, ASSESSMENT, AND PRIORITIZATION—EXAMPLES AND OPTIONS

Once chemicals are screened, assessed, and prioritized (though, as noted previously, it is not a linear process), decisions must be made. Data collection and evaluation are of limited value if not applied in decision-making processes. Traditionally, decisions on chemicals have not been made until extensive risk assessment and cost-benefit analysis processes are undertaken. Under many existing regulatory structures for chemicals management, the decision to act may be on the basis of chemical risk alone or the basis of chemical risk combined with economic and technical feasibility questions, including the availability of alternatives. In the former case, the economic and technical feasibility questions become part of the assessment process but only once a decision to act has been made (such as under the CEPA in Canada). In the latter case, these issues are weighed directly in the decision of an “unreasonable risk,” as is the case under TSCA. These traditional decision-making processes have proved slow and ineffective at facilitating rapid decisions on multiple chemicals and state government agencies often do not have the resources for them. Thus, there is a need for more rapid decision-making processes to facilitate actions on the basis of screening, assessment, prioritization processes noted above.

Making decisions does not require perfect information; indeed, demands for perfect information may inhibit preventive decision-making (traditionally uncertainty has favored further study, which means continued exposure to a potentially harmful chemical). As a result, it is necessary to act with precaution when making decisions in the face of uncertain chemical information. Under a more precautionary approach to decision-making, a decision to act should not be made only on the basis of risk but also should be a function of other considerations such as the availability of alternatives, the level of uncertainty about the chemical’s hazard and exposures,

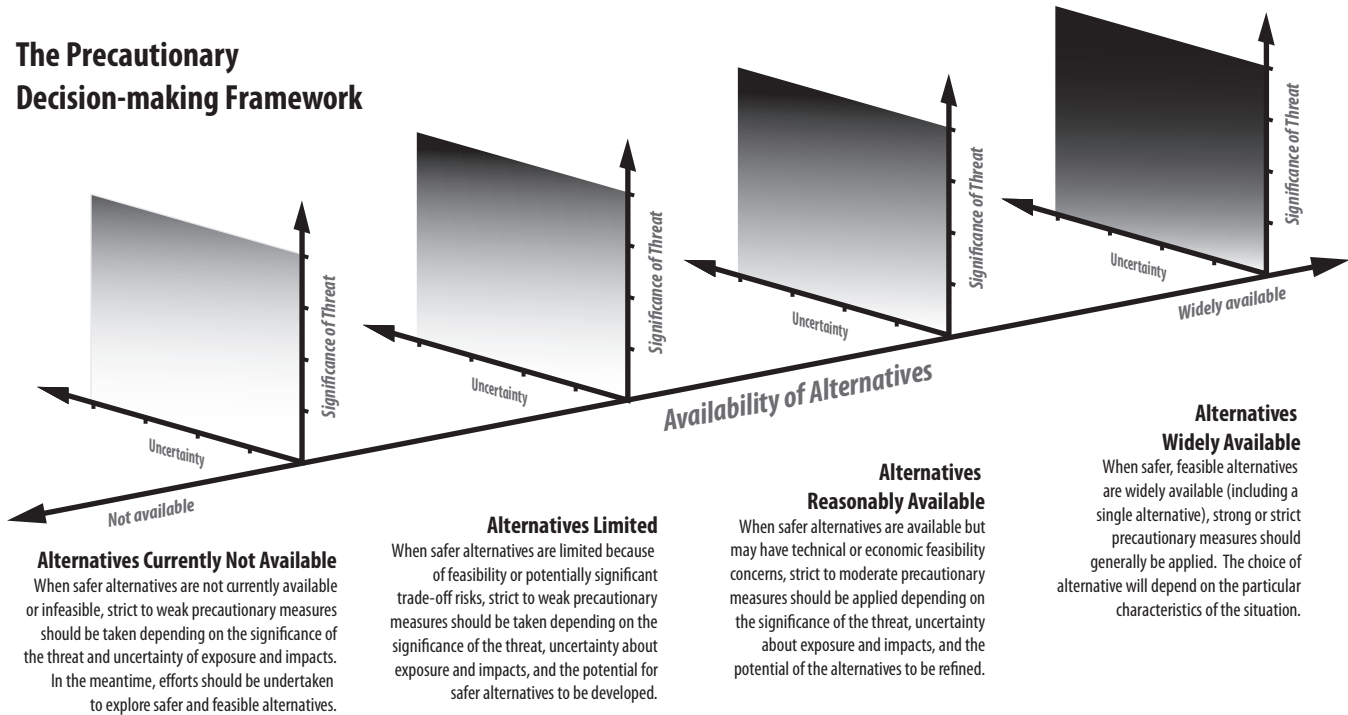
and the magnitude of the risk (for example, are there particularly sensitive populations at risk or if there is delay in action could any problems persist for long periods of time). Availability of feasible safer alternatives may warrant more rapid action on the basis of less detailed assessment and is one way to prioritize actions (see Module 4, Rossi). For example, despite uncertainties the Danish government restricted phthalates in children's toys, not on the basis of a quantitative risk assessment but rather on the basis of a series of considerations including: 1) evidence of toxicological hazard; 2) evidence of exposure to children; 3) children's unique sensitivity; 4) availability of alternatives; 5) the lack of a need for soft teething toys. Similarly, despite any evidence of human harm, actions were taken in Sweden on the polybrominated diphenyl ethers based on the fact that they were building up in breast milk (exposure concern), some toxicological evidence, and evidence of alternatives.²⁰

Tickner (2000)²¹ developed a tool called Precautionary Assessment to integrate rapid chemical assessment and alternatives assessment to facilitate decision-making in the face of uncertainty. Under Precautionary Assessment, the determination of actions is not based on a specific threshold for action but rather considers all of the available evidence in determining the most health-protective, yet reasonable, course of action. Policy tools for implementing precautionary action and preventing harm, ranging from further study to phasing out a chemical, are chosen based on the magnitude of the potential problem, uncertainty involved, and availability of feasible alternatives (See Figure 1). Decisions made under a precautionary assessment should not be considered permanent, but part of a continuous process of increasing understanding and reducing overall impacts. For example, some inherently dangerous chemicals may be integral to a particular process or may be the best choice at a given point in time from a lifecycle perspective (for example, mercury in compact fluorescent light bulbs reduces energy and use of coal-fired power plants), so chemicals policy efforts should be focused on minimizing potential impacts through the lifecycle of the material, improving efficiency of use, developing take-back schemes, and so forth. Once precautionary actions have been chosen, follow-up and monitoring schemes for the activity should be developed (using, for example, health and environmental indicators and surveillance). This type of feedback is critical to understanding the impacts of precautionary actions, as well as to provide early warnings of harm, thus helping to avoid unintended consequences. It also stimulates continuous improvement in environmental performance and technological innovation. For many substances, collection processes must be developed to ensure that the substance is not reintroduced into the environment as a waste product (for example mercury products). For other substances, technical assistance efforts must assist firms and workers in transitioning to alternatives (See Rossi, Module 4).

A determination of a level of precautionary action to be taken should be integrally linked with specific policy tools. Ideally, decision-making will be facilitated if decisions can be made on the basis of groups or broad classes of chemicals or hazard characteristics. The Box following outlines a non-exhaustive list of types of decisions that could be made on chemicals or groups of chemicals. Some could occur earlier or later in decision-making processes, for example, decisions to list chemicals of concern may occur more rapidly than decisions to phase out a substance. In all cases, developing means to enhance public participation in decision-making should be a clear goal of chemicals policy initiatives.

FIGURE 1 **Graphic Illustration of Precautionary Assessment**²¹

Under this framework the appropriate measures are a function of the significance of the threat, uncertainty, and the availability of safer alternatives. Significance of threat is a function of hazard, exposure, and magnitude of potential impacts. The darker color indicates the extent to which precautionary measures should be taken — from strict (restrictions) to weak (additional targeted study).



Types of Decisions that Can be Made on Individual or Groups of Chemicals

Strict precaution

- Mandated phase-out/sunsetting of a chemical or class of chemicals
- Mandated implementation of alternatives/substitutes

Strong precaution

- Chemical authorization schemes—reverse onus
- Negotiated phase-out/sunsetting of a chemical or class of chemicals (for example, voluntary action programs such as those undertaken for PFOA/PFOS or PBDEs where industry agrees to reduce exposure or uses)
- Negotiated implementation of alternatives/substitution
- Required establishment and implementation of use reduction goals
- Mandated substitution/pollution prevention planning with reduction goals or other incentives
- Temporary restrictions pending further testing
- Use restrictions (for example, no carcinogens in workplaces or in cosmetics)
- Procurement requirements (for example, green cleaners)
- Extended producer responsibility requirements*

Moderate precaution

- Development and publishing of a list of higher concern chemicals or categories of chemicals of concern — such as the Nordic Observation lists — that can be used to work with industry to identify alternatives or in permitting and inspection activities
- Placing the chemical on a list of chemicals for reporting, such as the Toxics Release Inventory
- Assurance of bonding or insurance requirements (liability if damage occurs)
- Strict exposure/emissions standards that force technology
- Mandated prevention/clean production planning without reduction goals or other incentives to improve efficiency in use
- Labeling requirements
- Information disclosure requirements — use, toxicity, supply chain information
- Development of product or chemical use registries to track chemicals in commerce
- Voluntary technical/research assistance to companies on safer alternatives
- Supply chain/stakeholder partnerships for alternatives (such as EPA Design for Environment partnerships)
- Demonstration projects on safer alternatives/award programs for leaders
- Research funding for safer alternatives/design change, such as government-sponsored challenge programs
- Ecological taxes — taxes on chemicals identified as problematic
- Rapid evaluation process to identify chemicals of higher and lower concern — voluntary or regulatory
- End-of-life collection activities

Weak precaution

- Voluntary data call-in initiatives on chemical hazard or use or exposure
- Further study to more specifically look at the extent of risk, particularly vulnerable sub-populations or economic or technical feasibility of alternatives (though some interim action may be taken with further study — such as listing or a notice to manufacturers and users of a chemical)
- Mitigation and control technology requirements
- Compensation for harm and clean up
- Fines
- No action (an action in and of itself)

* Extended producer responsibility is the concept whereby manufacturers have responsibility to “take back” their products at the end of their useful lives. The approach encourages reductions in hazardous materials.

As noted, state agencies rarely have resources for extended risk assessment/management processes on a chemical-by-chemical basis. Thus, tools to expedite decision-making on chemicals on the basis of scientific analysis are critical for states. There are various options for expedited chemicals decision-making that could be instituted. They include:

OPTION 1: Government initiates “authorization” requirements for chemicals identified as higher concern. Such an approach would treat chemicals of higher concern like drugs, whereby companies that wish to use these chemicals in manufacture or products would have to solicit “authorization” from a state government authority. Such authorizations could be time-limited in nature and could be granted on the basis of adequate documentation that the chemical is used in a safe way or that there are no technically or economically feasible alternatives. The strength of this option is the ability to have greater regulatory review over chemicals of very high concern (so that they are regulated as the general public currently believes they are). The process of seeking authorization would provide an incentive to identify safer alternatives. The limitation of this option is the amount of technical resources to implement it — for example, registering chemicals in products that are imported from other states; enforcing authorization requirements; reviewing requests for authorization, and so on.

Example of Option 1: The REACH Authorization Process.²²

Under REACH, chemicals of very high concern — those that are persistent, bioaccumulative and toxic (PBTs); very persistent and very bioaccumulative (vPvB); carcinogens, mutagens and reproductive toxicants; and other chemicals of high concern, such as endocrine disruptors — will be subject to authorization requirements. Under these requirements, companies wishing to use a chemical will have to seek authorization for that particular use (a particular manufacture of the substance can request authorization for a group of uses). For non-PBT and non-vPvB substances, a company can receive authorization if “adequate control” is demonstrated. If “adequate control” cannot be demonstrated, or the “adequate control” route is not available (PBTs and vPvBs) then a decision on authorizing a use will take account of the risks posed by the substance, socio-economic impacts of authorizing the use or not, possible alternatives and substitutes (substances and processes). Authorizations will be time-limited in nature and in granting an authorization the applicant must undertake a substitution analysis to identify potential substitutes that could be implemented in the future. The dates for authorization requirements have not been set and the process will likely be undertaken on a case-by-case basis over time. The European Commission will in the meantime publish a list of Substances of Very High Concern that will serve as a guide to firms and designate chemicals that will be heavily scrutinized.

OPTION 2: Government develops regulatory risk management programs for chemicals identified in screening and prioritization as being of higher concern. Under this option, government agencies would develop regulations to restrict particular uses of chemicals of high concern or emissions of those chemicals or initiate requirements for continued use (such as

labeling, chemical use data provision requirements, pollution prevention planning, and so forth). Several states currently have laws on the books allowing restrictions of chemicals of high concern, such as mercury and polybrominated diphenylethers, particularly when high-risk populations such as children are exposed. Most states undertake state implementation plans under the Clean Air Act that could allow emissions restrictions on certain chemicals. Further, states have extensive discretion in permitting decisions to require limitations or substitution planning for chemicals of high concern. Certain states, such as Massachusetts, have mandatory pollution prevention planning requirements that have provisions for additional requirements for sectors or chemicals of higher concern. Finally, states have jurisdiction under some laws to require clean-up activities for certain chemicals. The strength of the regulatory risk management approach is the ability to affect whole sectors and ensure broader compliance (everyone would have to comply). The weakness of such an approach is that agency resources needed to implement regulations may be extensive and require specific enabling legislation. The ability of an agency to act under current legislation may be hindered by burdens of evidence that must be presented (which would be hard to do after only a screening-level risk assessment process).

OPTION 3: Government issues a list of chemicals of high concern, lower concern, and further study and develops voluntary or regulatory programs/activities to develop data and move firms away from those chemicals. Under this approach, government agencies would develop and publish a list of chemicals of very high concern and work with industry to engage them in finding and implementing alternatives on a voluntary basis. States could work on voluntary action plans for chemicals of high concern (regulatory action plans may not be possible without specific legislation) where alternatives for the chemical are identified and particular action steps outlined, including demonstration projects, state procurement programs, data collection challenges on use data or alternatives; industry supply chain dialogs. The strength of such an approach is its positive and voluntary nature — the list of chemicals of higher concern can send strong market signals and government efforts can engage industry in identifying and implementing alternatives. The limitation of the approach is the problem of free-riders (companies that do not engage in the voluntary efforts) and the technical, financial, and human resource needs for agencies to implement such voluntary efforts. Nonetheless, the resources should be less than in a mandated action plan.

As an alternative to such an approach, states could develop mandatory action plans for chemicals of high concern that include action steps as noted above, joined with mandatory requirements for substitution. Such an approach is closely aligned with approaches underway in Denmark (for example, an action plan for phthalates) and in the state of Washington (for mercury and PBDEs).

Example of Option 3: Dutch Quick Scan.²³

The Dutch Ministry of Housing, Spatial Planning and the Environment developed Quick Scan as a method for prioritizing assessment and management of chemicals in commerce. While tech-

nically a screening tool, the Dutch government viewed Quick Scan as a decision-making tool. The approach uses existing data and includes criteria for a number of human health, ecological health, and physical property criteria. Chemicals are evaluated on the basis of those criteria and categorized into four hazard levels. Then, a qualitative risk assessment is conducted for each chemical using surrogates for exposure such as consumer use, industrial use, site-limited intermediate, and open application/professional use (see Appendix). Based on that assessment — conducted by industry — chemicals fall into a series of categories. It was the intention (Quick Scan has been superseded by the EU REACH program) of the Dutch government that Quick Scan would serve as the basis of voluntary sector-based initiatives in chemicals reduction, cleaner production, and public procurement.

Example of Option 3: Swedish PRIO²⁴ database.

PRIO is a web-based tool intended to be used to preventively reduce risks to human health and the environment from chemicals. PRIO replaces the Swedish Chemicals Inspectorate's Observation (OBS) list. The aim of PRIO is to facilitate the assessment of health and environmental risks of chemicals so that people who work as environmental managers, purchasers, and product developers can identify the need for risk reduction. To achieve its goal, PRIO provides a guide for decision-making that can be used in setting risk reduction priorities. The PRIO database contains chemicals identified as being of high concern by the government (phase-out or risk reduction). It allows users to search for substances and obtain information on properties; identify substances contained in product types; and obtain help in developing support for product development. The Swedish government is using the results of PRIO to target technical assistance, procurement, and other voluntary efforts.

OPTION 4: Government initiates voluntary industry self-classification challenge to self-classify and reduce use of chemicals of high concern. Government agencies would provide tools to industry and “challenge” companies to self-classify chemicals, develop lists of chemicals of concern, and to develop action plans for reduction of such chemicals. Government agencies would provide categorization tools, technical support, and incentives (such as awards and regulatory relief) to firms taking part in the challenge. Its strength is the limited government resources needed for its implementation (it relies primarily on industry but would require technical assistance resources from government). The approach is also positive in nature and would help institutionalize chemical safety thinking in the firm rather than serving as a restrictions hammer. The drawback is that laggard companies will have little incentive to participate. This problem could be addressed through disincentives for non-participation. Further, another drawback is potential lack of accountability. Having strong data and information provision as part of any voluntary program is critical to ensure transparency.

Example of Option 4: UK COSHH Essentials.²⁵

The UK Health and Safety Executive has developed the COSHH Essentials, based in the Control of Substances Hazardous to Health Regulations (COSHH). It is an internet-supported method

for health risk assessment of chemicals used in industry as well as advice for workers and firms' personnel in control, good use practices, and training. Users provide information on the chemical or chemicals of interest (including chemical and physical properties), the risk phases, the production process and the way in which the chemical is used, and quantities used. The tool provides recommendations for controls and hazard information for the chemical and possible alternatives. The user is provided a downloadable report with the recommendations.

Example of Option 4: SC Johnson Co. Greenlist.²⁶

SC Johnson Company developed Greenlist as a comparative method to measure the environmental impacts of chemical choices. SC Johnson uses Greenlist to measure progress towards sustainability goals and has provided access to its process for any firm wanting to use the tool and commit to implementing the results. SC Johnson has developed four to seven criteria for different types of chemicals (for example, surfactants, solvents) used in products, including biodegradability, aquatic toxicity, human toxicity, vapor pressure, and other significant concern (banned elsewhere, a PBT, carcinogen, and so forth). These criteria depend on chemical type and use. Chemicals within a category are then scored 0 (restricted use) to 3 (best) for the various criteria and a weighted score is developed. The goal is to avoid chemicals scored 0 or 1 and to keep moving towards the chemicals scored as 3. SC Johnson allows other companies to use Greenlist free of charge on the condition that they commit to benchmarks for reducing chemicals listed as 0 or 1.

Example of Option 4: McDonough Braungart Design Chemistry (MBDC) Cradle to Cradle Design and Material Assessment Protocol.

MBDC has developed this pay-for-use protocol to assess materials used in products and processes in order to assist companies in designing more environmentally friendly products. The Protocol considers human and ecological health end points as well as recyclability, recycled content and/or use of renewable resources, product design and disassembly). It does not examine exposure. Chemicals are rated qualitatively on the basis of their hazard characteristics: Green — little or no risk; yellow — low to moderate risk; orange — data lacking to estimate risk; red — high risk. MBDC has developed criteria for each endpoint that would indicate into which category a particular chemical would fall.²⁷

Example of Option 4: Clean Production Action's Green Screen.²⁸

Clean Production Action has developed the Green Screen as a hazard prioritization and decision-making process for chemicals. Green Screen provides a hierarchy of hazards (for instance, persistence and bioaccumulation) and decisions to be made based on hazard characteristics. Users gather data about a chemical and then enter available information on their chemical into the Green Screen to determine whether it is a chemical of high concern (stop using) or lower concern.

OPTIONS FOR CHEMICALS DECISION-MAKING

This table summarizes the four options for chemical decision-making outlined above with regard to speed, cost, resource needs, transparency, and performance. L=low; M=medium; H=high

	Option 1: Government initiates "authorization" requirements for chemicals identified as higher concern	Option 2: Government develops regulatory risk management programs for chemicals identified in screening and prioritization as being of higher concern	Option 3: Government issues a list of chemicals of high concern, lower concern, and further study and develops voluntary programs/activities to develop data and move firms away from those chemicals	Option 4: Government initiates voluntary industry self-classification challenge to self-classify and reduce use of chemicals of high concern
Speed of implementation	L	L/M	M/H	M
Cost				
Industry	H	H	M	M/H
Government	H	H	M	L/M
Technical/human resource needs				
Government	M/H	M/H	M	L
Industry	H	M	M	M/H
Public access to information/transparency	M	M/H	M	L
Performance – ability to expedite decisions and lead to implementation of safer chemicals and uses	M/H	M/H	M/H	M

Considerations in Decision-Making

Multiple considerations must be addressed in the decision-making stage:

- **The legal framework.** In the end, the ability of an agency to make decisions (particularly regulatory ones) will depend on the existing legal framework. An agency must have authority (ability and resources) to undertake a regulatory initiative that involves decision-making on chemicals (for example, restrictions). Such a legal framework lays out the thresholds for action (that is, evidentiary needs, other considerations — such as economic and technical feasibility — that must be taken into account). Even voluntary programs could be subject to some type of budgetary review.

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- **Whether decisions should be hazard- or risk-based.** As described in the previous section, a decision to identify a chemical of higher concern is often a hazard-based determination. Prioritizing uses of highest concerns may include qualitative risk information. The decision whether to base decisions on hazard or risk may depend on the regulatory framework. For certain types of chemicals — such as those that persist or bioaccumulate — hazard alone should be sufficient to implement substitution type decisions.
 - **How much data are needed to make a decision?** In many cases, screening level may not be sufficient for regulatory decision-making (if laws have decision-thresholds) but could be sufficient for requesting voluntary measures on the part of industry (particularly if characteristics of concern are identified), placing the chemical on a list of high concern, labeling requirements, and so on. A particularly important point in determining how much data are needed is the availability of prevention options or other drivers such as regulations in another jurisdiction. For example, for a chemical that has little data or just a screening-level review, regulations in Europe will be enough to initiate voluntary programs in order to maintain markets for state-based industries. Similarly, the availability of a safer alternative (particularly if it is being manufactured in the state) may provide an additional incentive to undertake a demonstration program.
 - **Who should make the decisions — government, industry?** There are pros and cons to industry versus government making decisions. The strength of government decisions — particularly those listing chemicals of concern — are that they provide a broad signal to markets of actions that could be taken in the future (including changes to procurement practices). This would allow for a consistent list of chemicals of high concern. The benefit of industry making decisions is that companies know their particular chemical uses, options for reduction, and so forth and may be able to more quickly prioritize a broader range of chemicals based on their uses than government. Also, actions undertaken by the company may have a better chance of resulting in prevention activities versus a mandate (even listing) from government. Many firms are expressly opposed to listing chemicals. Thus, placing all decision-making authority on industry without a requisite incentive (stick) to implement change may be insufficient.
 - **To what extent should concerns about risk trade-offs, feasibility, and socioeconomic impact be considered?** A decision is not a good decision if it results in firms switching from one chemical of concern to another. Thus, clear guidelines about which chemicals are of higher and lower concern are critical, as well as guidelines on comprehensive alternatives assessments to consider trade-offs in reduction and substitution decisions. The extent to which technical and economic feasibility must be considered will depend on the type of decision — that is, a regulatory restriction versus a voluntary initiative. In a regulatory initiative, it would make sense to consider the viability of alternatives so that firms do not simply switch to the next slightly less problematic alternative. In a voluntary effort, companies will not undertake the action if it appears to cost too much or is not viable. In both cases, government-supported research, technical support, and demonstration can help to address these issues of technical risk increasing the viability of options.

- **What to do with chemicals of lower concern at the moment?** Some chemicals — through either assessment or prioritization processes — will be considered lower concern. However, that may be based on an initial screening-level analysis of data. As such, processes need to be in place to collect additional data if new evidence emerges about the toxicity of a lower concern chemical. Lower concern is not equivalent to no concern or no risk management measures needed. At the same time, having a list of lower concern chemicals is important (if good data are available to verify that they are indeed lower concern) to provide signals of the types of preferable chemicals for particular functions.
- **Voluntary versus mandatory actions.** There are pros and cons to voluntary versus regulatory actions at the decision-making stage on chemicals. Mandatory actions tend to level the playing field (apply broadly to a range of actors), set clear requirements, and have the force of law behind them (objectives and enforcements). To date, mandatory requirements on chemicals have generally been focused on single chemicals. However, they can be confrontational and become tied up in litigation. Voluntary initiative, on the other hand, can be more flexible in nature, have more aggressive goals, and address a broader range of materials in a more rapid manner. However, they can suffer from the “free rider” syndrome of those not wanting to participate voluntarily and lack of follow through. Hansen and Tickner²⁹ have noted a series of considerations when designing voluntary initiatives, including: 1) incentives to participate for various stakeholders — and disincentives to non-participation; 2) agency guidance and technical assistance; 3) signed commitments and periodical reporting; 4) measures to ensure quality of information; 5) transparency in design, reporting, and evaluation; and 6) links to regulation if voluntary efforts do not achieve their goals. A hybrid is the idea of a consent agreement where industry and government (and other stakeholders) negotiate performance targets and deadlines in a binding manner. In all cases, agencies have substantial discretion to issue clear statements and recommendations and in permitting to send strong signals in a voluntary program.

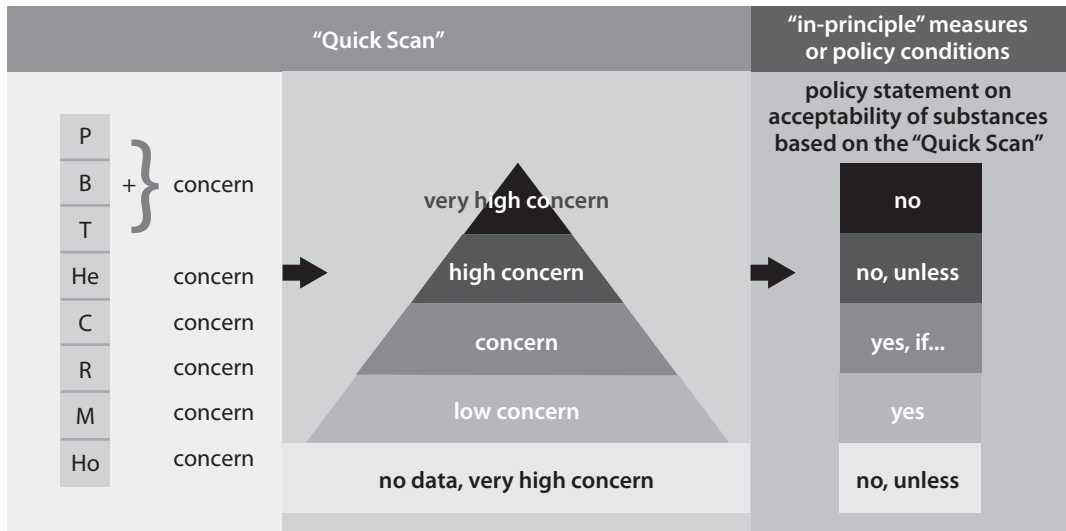
When a mandatory versus voluntary initiative makes sense depends on the particular issue. The key considerations seem to be: 1) speed of implementation and action; 2) resources for implementation/enforcement; 3) scope of sectors or chemicals to be targeted; 4) ability to engage industry effectively with possibility for success and limited free riders; and 5) ability to support those firms most committed to safer chemicals and materials while bringing along laggards. Many firms welcome mandatory requirements, particularly if they are the producer of the alternative, as they will enhance their ability to market a safer product. If the goal is to phase out a chemical used in multiple sectors, a mandatory approach would make more sense, ensuring broad application. If a chemical is only produced by a small number of manufacturers (and is the only source of that substance) a voluntary consent agreement, as was the case for the PentaBDE may make more sense, given the speed of implementation. If the goal is to institute more rapid decisions, internalizing thinking about safer chemicals in a broad range of firms, a challenge type program, mandating some kind of planning/prioritization process but allowing ultimate decision-

making to the firm, may make the most sense. The process of requiring firms to rapidly evaluate chemical hazards and alternatives may be sufficient to stimulate implementation of safer alternatives.

CONCLUSION

The process of screening, assessment/prioritization, and decision-making is not a linear or always clear process. In this module, we have laid out several overlapping options with the goal of expediting decisions on a wider range of chemicals at a state level. Clearly, the options outlined extend across screening, assessment and decision-making but it is important to focus on the overall goal of facilitating the process of characterizing chemical hazards/risks and actions to reduce the use, exposure to, or substitute for chemicals of concern. In general, processes which provide strong signals to industry of chemicals deemed of higher concern to the state, coupled with procurement guidelines, technical assistance programs and other pollution prevention type efforts, seem to be the least expensive and quickest way to facilitate actions at the state level. Detailed registration, risk assessment, and authorization type programs may not make much sense at the state level given the extensive economic and technical resources needed. They generally make more sense at a federal level. However, some regional type initiatives where resources are combined between states, such as a regional model of the Canadian DSL categorization approach may make sense. Given the number of chemical categorization and prioritization processes that have taken place in the U.S. and beyond, states could utilize the work of other locations and pull them into a single interstate clearinghouse, thus obviating the need for undertaking their own processes. However, undertaking state-based processes with the involvement of multiple societal stakeholders may provide a greater ability to effect change.

Appendix: Dutch Quick Scan Model



Substances in concern category on basis of hazard and use

CONCERN ON BASIS OF HAZARD	EXPOSURE ON BASIS OF USE	Use of substances as indication of exposure			
		Site limited intermediate substances	Substances in industrial applications	Open professional use of substances	Substances in consumer applications
	Low Exposure	Exposure	High Exposure	Very High Exposure	
Very high concern	High concern	High concern	Very high concern	Very high concern	Very high concern
High concern	Concern	Concern	High concern	High concern	High concern
Concern	Concern	Concern	Concern	High concern	High concern
Low concern	Low concern	Low concern	Low concern	Concern	Concern
No data, very high concern	Very high concern	Very high concern	Very high concern	Very high concern	Very high concern

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MODULE 4

Policy Options for Chemical Substitution and Alternatives Assessment: Defining Environmentally Preferable Solutions

■ MARK ROSSI

What is substitution in chemicals regulatory policy and how can states find the best alternatives for hazardous or risky substances used in production and commerce?

Chemicals of high concern to human health and the environment often remain on the market and in use, despite the availability of alternatives. Performance, cost, availability, technology lock-in, and lack of information on alternatives in combination with aggressive market defense by manufacturers keeps toxic chemicals on the market even when safer alternatives are in use, perform comparably, and are cost competitive. In addition, government incentives are limited for researching, developing, and adopting safer alternatives. The challenges policy-makers confront are how to enhance the capacity and will of chemical producers to manufacture, and chemical users to adopt, safer alternatives.¹

The goal of chemical policy reform should be to move the economy away from chemicals that are harmful to human health and the environment to chemicals that are safe and healthy. Sweden, for example, has set a goal of achieving a non-toxic environment by 2020: “The environment must be free from manmade or extracted compounds and metals that represent a threat to human health or biological diversity. This objective is intended to be achieved within one generation.”²

Shifting the economy away from toxic to safer chemicals requires **substitution**: “the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures.”³ Without substitution of safer alternatives, toxic chemicals will continue to be manufactured, used, and disposed of resulting in adverse effects to humans and the environment. Thus, policies are needed to increase the supply and demand for safer substitutes.

“Substitution” is a broad term, encompassing changes in materials, products, production processes, and design (for example, design out the need for a chemical, such as a flame retardant, in a product), as well as changes in chemicals. Thus implementing substitution may result in the use of a different chemical (a chemical-to-chemical substitution) or it may result in the use of a different material or product that eliminates the need for the chemical in the first place (a chemical-to-material or chemical-to-product substitution).

How businesses implement substitution varies depending on their stage in the lifecycle of a toxic chemical. For chemical manufacturers, substitution entails creating research and development processes that foster the production of inherently safer chemicals. The 12 Principles of Green Chemistry provide a guide to manufacturers on how to design safer chemicals, including:

- Principle #2: “Design chemical products to be fully effective, yet have little or no toxicity.”
- Principle #4: “Use renewable feedstocks.”
- Principle #5: “Use catalysts, not stoichiometric reagents.”
- Principle #8: “Use safer solvents and reaction conditions.”
- Principle #10: “Design chemical products to break down to innocuous substances after use.”⁴

For intermediate users (such as plastic compounders who mix additives into plastics) and manufacturers of final products, substitution entails changing products and production processes to avoid the use of toxic chemicals. And for buyers of products, substitution entails changing purchasing specifications to avoid toxic chemicals and prefer safer chemicals, materials, and products.

The process by which manufacturers and chemical users decide how to select an appropriate substitute to a hazardous chemical is an example of **alternatives assessment**: a method for evaluating and identifying an environmentally preferable substitute(s).⁵ Alternatives assessments for chemical manufacturers involve: 1) creating new chemicals and production processes based upon the principles of green chemistry, 2) evaluating the hazards of the new chemicals across their lifecycles, and 3) working with end users to meet their technical performance needs.

Research on chemical users and institutional purchasers (for example, hospitals or governments) reveals the process, the steps, they are taking to implement substitution.⁶ Businesses that use or purchase products that contain toxic chemicals implement substitution through a set of data gathering, analytic, and action steps:

1. Identify all the chemicals used in the manufacture of the product, including the material chemistry⁷ of the product.
2. Evaluate the hazards of those chemicals.
3. Classify the chemicals into levels of concern (for example, high, moderate, or low concern).
4. Identify alternatives to chemicals of high concern.
5. Work with suppliers to provide preferred alternatives.
6. Evaluate, compare, and prioritize alternatives.
7. Select preferred alternative—substitution.

This module uses alternatives assessment to frame policy options for promoting and requiring safer substitutes. The section called Policy Options for Chemical Substitution and Alternatives Assessment identifies policy options for addressing each step in the alternatives assessment process for chemical users (which overlaps with the assessment process for chemical manufacturers), with particular attention paid to policies that achieve multiple steps in alternatives assessment. The following section addresses the challenging question, “what is a safer alternative?” And the last section summarizes the effects of policy options, including costs and outcomes.

POLICY OPTIONS FOR CHEMICAL SUBSTITUTION AND ALTERNATIVES ASSESSMENT

If the goal of chemical policy reform is to use chemicals that are healthy for humans and the environment, if substitution is the means for achieving this goal, then policies are needed that encourage, support, and in some cases, require substitution. Governments advance the practice of substitution in business by adopting and implementing policies that support each step in the alternatives assessment process. Success in substitution will require a package of policy initiatives that provide information, create incentives for safer alternatives and disincentives for using/producing chemicals of high concern, and require action.

Table 1 (following) lists the policy options (in the first column) that support steps in the alternatives assessment process. The first set of policies, “chemical use information,” requires companies to provide data on the hazards posed by chemicals and products and involve creating databases of products that contain hazardous chemicals. The second set, “chemical hazard data and classification,” involves the collection, evaluation, and dissemination of chemical hazard data by government agencies. The third set, “supply-side options,” creates incentives, information, and technologies that support the generation of environmentally preferable chemicals. The fourth set, “selection policies,” involves government either purchasing or promoting the purchase of environmentally preferable products. And the fifth set, “multi-attribute options,” is policy options that address multiple steps in alternatives assessment. Each of these sets of policy options is examined below in more detail.

Chemical Use Policies

At the entry level to alternatives assessment is ascertaining which chemicals are in or used to manufacture a product. A few product manufacturers, including Herman Miller and Interface Fabrics, require their suppliers to disclose the chemical constituents of all the materials used to manufacture a product. Yet, tracking down chemical constituent information for most manufacturers remains a challenge, as these comments from Tom Cooper of Kaiser Permanente’s Strategy, Planning, and Design team illustrate: “Obtaining information about the chemicals in products is very difficult,” Cooper said. “Passing legislation that would require companies to disclose the chemicals in their products to end users and to consumers would be helpful,” he said.”⁸

TABLE 1 Policy Options to Achieve Substitution

Policy Options	Steps in Alternatives Assessment							Policy Examples
	1. Identify Chemicals in Products	2. Evaluate Hazards	3. Classify Chemicals	4. Identify Alternatives	5. Work with Suppliers	6. Evaluate & Prioritize Alternatives	7. Select Alternative—Substitution	
1. Chemical Use Information								
Chemical disclosure	X							Material Safety Data Sheets (MSDSs)
Chemical use database	X							Maine Mercury-Added Products Act
Warning labels	X	X	X					California Proposition 65
2. Chemical Hazard Data and Classification								
Evaluate chemical hazards		X						US EPA DfE Program and P2 Framework tools
Comprehensive hazard data		X	X					US EPA HPV data and EU REACH
Classify chemicals			X					EU REACH
3. Supply-side Options								
R&D support				X				EU SusChem
Green chemistry centers				X				New England Green Chemistry Consortium
Tax credits				X				New York Green Building Tax Credit
Taxes and fees				X				Danish Greenhouse Gas tax and TURA
4. Selection Policies								
Eco-labels							X	EU Flower, Nordic Swan, Energy Star
Government procurement							X	EPP programs in many states & cities
5. Multi-Attribute Options								
Alternative assessments	X	X	X	X	X	X		TURI Alternatives Assessment and US EPA DfE Program
Technical assistance	X	X	X	X	X	X		MA TURA and many other state TAPs
Substitution plans	X	X	X	X	X	X	X	MA TURA and EU REACH
Chemical restriction / Substitution requirement	X	X	X	X	X	X	X	Clean Air Act Amendments of 1990–Title VI; US FQPA; EU REACH

Abbreviations: DfE–Design for Environment; EPP–Environmentally Preferable Product; EU–European Union; FQPA–Food Quality Protection Act; HPV–High Production Volume; MA–Massachusetts; P2–Pollution Prevention; REACH–Registration, Evaluation, and Authorisation of Chemicals; SusChem–Technology Platform for Sustainable Chemistry; TAPs–Technical Assistance Programs; TURA–Toxics Use Reduction Act; TURI–Toxics Use Reduction Institute; and US EPA–US Environmental Protection Agency.

Governments facilitate the availability of information on the chemical constituents in products by:

- Requiring ingredient disclosure,
- Creating databases on chemical uses, and
- Requiring warning labels for products that contain chemicals of high concern.

Chemical ingredient disclosure refers to the listing of chemicals — ideally by CAS registry number (CASRN) — on a product, including the chemistry make-up of materials in the product such as additives in plastic materials. To date, manufacturers of most products are not required by government to provide such data.

Chemical manufacturers and importers are required by the Occupational Safety and Health Administration (OSHA) to provide material safety data sheets (MSDSs) when they sell hazardous chemicals to distributors and employers. For chemical mixtures, the MSDS must include:

The chemical and common name(s) of all ingredients which have been determined to be health hazards, and which comprise less than 1% (0.1% for carcinogens) of the mixture, if there is evidence that the ingredient(s) could be released from the mixture in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH [American Conference of Governmental Industrial Hygienists] Threshold Limit Value, or could present a health risk to employees.⁹

But MSDSs are notorious for problems related to accuracy, consistency, and comprehensiveness.¹⁰

Chemical use databases. Given the lack of publicly available data on chemical uses, governments are creating databases for certain chemicals of high concern. For example, the Northeast Waste Management Officials' Association (NEWMOA) has created, in collaboration with states across the country, the Interstate Mercury Education and Reduction Clearinghouse (IMERC) Mercury-Added Products Database to provide information on the amount and purpose of mercury in consumer products.¹¹

Warning labels on products that identify specific chemicals is another route to providing limited information on the chemical content of products. Under Proposition 65 (Prop 65) in California, manufacturers are required to provide warnings on products that contain Prop 65 chemicals that can result in exposures of concern to human health. However, the warnings are not required to identify the chemical of concern. (Rachel Massey in Module 2 provides further details on how manufacturers can identify the chemical constituents of products).

The most comprehensive policy option for fulfilling the need for information on the chemical ingredients in products is requiring product manufacturers to disclose the chemical ingredients in products (similar to the requirements for processed food). The more plausible policy option is the approach taken by the states in IMERC on mercury, to create a database of end uses for chemicals of high concern, such as persistent, bioaccumulative toxics (PBTs).

Chemical Hazard Data and Classification Options

After identifying the chemical constituents of products, the next steps in alternatives assessment are to evaluate the hazards of the chemicals and to classify them to levels of concern. Governments assist companies in evaluating the hazards and potential exposures (including risks) posed by chemicals by:

- Evaluating the chemicals themselves,
- Creating tools for assessing chemical hazards and exposure, and
- Requiring (or working in voluntary collaboration with) businesses to provide hazard and exposure data.

Governments have evaluated in detail the risks posed by a relatively small number of chemicals. The European Union's Chemicals Bureau, for example, lists only 75 risk assessment reports on its web page.¹² However, as Richard Denison details in Module 1, **initiatives are underway to gather more data on chemical hazards.** The European Union (EU) now will require businesses to provide hazard and exposure data on chemicals sold in the EU. And in the U.S., the Environmental Protection Agency's (EPA) High Production Volume (HPV) program works voluntarily with manufacturers to collect chemical screening data.

Governments also are creating **tools and resources** to assist businesses in assessing chemical hazards and exposure (see Tickner, Module 3; Geiser and McPherson, Module 5). For example, the U.S. EPA Design for Environment (DfE) program has assessed the hazards alternatives to pentabromodiphenyl ether (pentaBDE) used in low-density foam pose to human and environmental health.¹³

Using some toxicity screening tools requires knowledge of chemistry and toxicology. Thus, these tools for screening chemical hazards and exposures are not readily accessible to many businesses, especially purchasers.

An important role for government is to use the data on chemical hazard and exposure and **classify chemicals into levels of concern**—for example, levels of high, moderate, low, and unknown concern. The greatest activity to date has been in identifying small numbers of high concern chemicals, for example those that are persistent, bioaccumulative, and toxic. The recently proposed Act for a Healthy Massachusetts: Safer Alternatives to Toxic Chemicals includes a section that requires the state's Toxics Use Reduction Institute (TURI) to publish a "Preliminary Chemicals Categorization List" that classifies chemicals used in the state into one of four categories: chemicals of high concern, chemicals of concern, chemicals of unknown concern, and chemicals of low concern.

Knowledge of the hazards and risks posed by chemicals is essential for chemical users and product purchasers when assessing the environmental preferability of products.

Supply-Side Policy Options (and Other Initiatives to Identify Alternatives)

Once chemicals of high concern are identified as targets for substitution, the next step in the alternatives assessment process is to identify potential alternatives. Governments support the identification of alternatives to chemicals of high concern by:

- Enacting policies that support the development of alternatives—supply side policies,
- Performing alternatives assessments, and
- Creating lists of alternatives.

In their module, Ken Geiser and Alexandra McPherson (see Module 5, Geiser and McPherson) detail the supply side policies governments can use to nurture the development of safer alternatives. These policies include research and development (R&D) support, technical and financial assistance, tax credits for environmentally preferable alternatives, and taxes and fees that create disincentives for the use of chemicals of high concern.

An example of taxes or fees on toxic chemicals is the Omnibus Budget Reconciliation Act of 1989, which levied an excise tax on ozone depleting chemicals. Another example is the recommendation by the International Joint Commission (IJC) to tax chlorine and the chlorinated plastic polyvinyl chloride (PVC) to facilitate the virtual elimination of chlorinated dioxins in the Great Lakes region and catalyze the development of safer substitutes.¹⁴ This recommendation, however, was not acted upon. A third example of taxes or fees is the 1996 decision by Denmark to shift revenue by reducing taxes on wages and increasing by the same amount a tax on carbon emissions, pesticide use, and chlorinated solvent use. Such “tax shifts” or “ecological tax reform” could be used to tax the halogen producers while subsidizing green chemical producers with this income.¹⁵

Identifying lists of alternatives usually occurs as part of a more comprehensive alternatives assessment, such as the U.S. EPA’s assessment of alternatives to pentaBDE (noted above) and TURI’s *Five Chemicals Alternatives Assessment Study*. These approaches are discussed in more detail below. That said, government programs could develop lists of alternatives to chemicals of high concern, similar to the CleanGredients™ online database of environmentally preferable institutional and industrial cleaning ingredients.¹⁶

Alternatives Selection Policies

Eco-labels and government procurement are two policy options where government becomes involved in product selection. Eco-labels define the environmental performance specifications a product must meet to receive the label. Government ecolabel programs include the Energy Star (U.S.), Blue Angel (Germany), Flower (European Union), Environmental Choice Program (Canada), Nordic Swan (Nordic Countries), and Ecomark (Japan).

In the context of chemicals, eco-labels can specify:

- Preferred attributes of chemicals used in the product (such as readily biodegradable),
- Negative attributes to be avoided, either in product or as emissions, or
- Specify the avoidance of specific chemicals (for example, mercury, lead, or polybrominated diphenyl ethers).

Eco-labels have many advantages. They are voluntary: businesses choose whether or not to design products to receive the label and whether to purchase products with the label. They can focus on the positive attributes of chemicals — low persistence, low toxicity, and readily biodegradable. They can encompass a range of environmental attributes, including energy and water consumption, use of renewable resources, as well as chemical hazards. And they raise consumer awareness.

In an assessment of business engagement in European ecolabel programs, Wurzel, et al. (2003) concluded that:

“The degree to which business finds eco-label schemes attractive depends most of all on the level of public environmental awareness in general and consumer awareness of the eco-label in particular. However, whether businesses apply for the eco-label or not often also depends on whether competitors make use of the eco-label for functionally equivalent products. **In general producers and service providers are more driven by fears about a loss in market shares rather than the hope of increasing their market share due to an eco-label award.** Once a critical mass of businesses has successfully applied for an eco-label within a certain market segment the remaining companies find themselves under considerable market pressure also to seek the label for their competing product(s). Market dynamics therefore explain why the eco-label has a very high uptake in certain market segments but fails to penetrate other market segments.¹⁷”

Government procurement uses the purchasing power of government institutions to drive product change. The federal government purchases more than \$200 billion worth of goods and services each year, with state and local governments purchasing more than \$1 trillion worth of goods and services each year.¹⁸ Like eco-labels, government procurement involves the incorporation of environmentally preferable product (EPP) specifications into contracts. In Massachusetts, EPP purchases by state agencies totaled \$92.5 million in 2001. A notable success of the Massachusetts program has been the virtual elimination of mercury-containing products from statewide contracts.¹⁹

EPP purchasing is a relatively low cost activity for government and business. In fact, the state of Massachusetts estimates that its EPP program saves money through the purchase of energy efficient office equipment and remanufactured toner cartridges.¹⁹ Typically government EPP programs do not generate innovations, but rather generate the diffusion of existing technology because acceptable bids usually require a minimum of at least two bidders.

Multi-Attribute Options—Policies that Support Multiple Steps in an Alternatives Assessment

A handful of policy options support many of the steps in an alternatives assessment:

- Government-sponsored alternative assessments,
- Technical assistance programs,
- Substitution plans by business, and
- Government required action—chemical restrictions or substitution.

As shown in Table 1, all of these policy options can support Steps 1–6 in an alternatives assessment. Substitution plans, substitution requirements, and chemical restrictions support Step 7 as well, leading to the selection and use of an alternative.

Government-Sponsored Alternatives Assessments: Government agencies like the U.S. EPA and public institutions like the Massachusetts Toxics Use Reduction Institute (TURI) perform alternative assessments of chemicals to inform policy-makers and businesses on the availability of safer alternatives. Both the EPA’s Design for Environment program and TURI have completed detailed alternatives assessments to chemicals of high concern.

The scope of alternative assessments to toxic chemicals includes at a minimum the hazards of the alternatives and may extend to include evaluations of exposure as well as the economic and technical performance of the alternatives. DfE’s assessment of alternatives to pentaBDE in low-density polyurethane foam focused on the hazards and exposure profiles of alternative flame retardants. TURI’s *Five Chemicals Alternatives Assessment Study* included identifying chemical uses, hazards, and alternatives; evaluating and comparing alternatives; and identifying potentially safer alternatives. In evaluating the alternatives, TURI included technical, environmental, and economic performance measures.

Alternatives assessments have the advantage of providing detailed data on the availability of alternatives. However, like risk assessments, they can be time- and resource-intensive (though not as resource-intensive as a typical risk assessment), which means that governments will be limited to the number they can complete. For businesses that manufacture or use chemicals that are the subject of a government alternative assessment, the costs are typically low, with modest investments in providing technical data to the government researchers.

Public involvement in alternatives assessment is typically limited to advocacy groups with expertise on the chemical(s) being discussed. The general public, which wants safer alternatives — as illustrated by growing demand for safer products such as organic foods — is not engaged in the nuances of debating hazards, exposures, costs, and technical performance of alternatives.

Government-completed alternatives assessments on their own, not in combination with other government action, are weak instruments for effecting technology change. The mere presence

of information — without other government action, including outreach and direct technical assistance to end users, labeling requirements, or substitution requirements — is unlikely to generate action. For example, the Swedish National Chemicals Inspectorate, in an assessment of environmental change in the information and communication technology (ICT) sector, concluded:

“What has become evident through the investigation of product environmental information flow and the linkage to product environmental improvements is that, **although information is important for product improvement, it is not the driver for the change.** From the finding in this report, it would appear that it is the key legislative, policy (WEEE, RoHS, IPP, EEE, etc.) and market driver (public & corporate purchasing) that are influencing product design, end-of-life management and subsequently driving environmental improvement in the ICT sector.²⁰”

Thus, alternative assessments must be linked to other government initiatives to produce technology change.

Legislative requirements that governments perform alternative assessments to toxic chemicals are often linked to chemical restrictions or substitution policies. Examples include: Restriction of Hazardous Substances Directive (RoHS–European Union); Clean Air Act Amendments of 1990–Title VI; the proposed Massachusetts Act for a Healthy Massachusetts: Safer Alternatives to Toxic Chemicals; and Registration, Evaluation and Authorization of Chemicals (REACH–European Union).

Under the **Restriction of Hazardous Substances (RoHS) in Electrical and Electronic Equipment (2002) Directive** exemptions to chemical restrictions are only allowed “if substitution is not possible from the scientific and technical point of view or if the negative environmental or health impacts caused by substitution are likely to outweigh the human and environmental benefits of the substitution.” This implies that a substitution assessment must be performed when a business applies for an exemption and alternatives are available. However, there have been glitches in the implementation of the substitution assessment part of the RoHS Directive, as exemplified by the decabromodiphenyl ether (decaBDE) exemption—which the EU granted despite not performing a substitution assessment.

Under the **Clean Air Act Amendments (CAAA) of 1990, Title VI–Stratospheric Ozone Protection** (which phased out the use of many ozone depleting substances), the U.S. EPA is responsible for identifying safe alternatives and assessing the hazards of alternatives, but is not required to perform economic assessments. Section 612 of Title VI establishes a “Safer Alternatives Policy,” defined as:

- a) **Policy.** To the maximum extent practicable, class I and class II substances shall be replaced by chemicals, product substitutes, or alternative manufacturing processes that reduce overall risks to human health and the environment.

Title VI delegates to the EPA responsibility for reducing overall risks to human health and the environment:

b) **Alternatives for Class I or II Substances.** Within 2 years after enactment of the Clean Air Act Amendments of 1990 the Administrator shall promulgate rules under this section providing that it shall be unlawful to replace any class I or class II substance with any substitute substance which the Administrator determines may present adverse effects to human health or the environment, where the Administrator has identified an alternative to such replacement that:

- 1) reduces the overall hazards to human health and the environment; and
- 2) is currently or potentially available.

In practice, the EPA identified alternatives to uses of ozone depleting toxic chemicals including solvents and evaluated their economic, technical, and environmental performance. In terms of environmental performance, the EPA focused on whether or not the alternatives were ozone depleting substances. Thus, “safer” came to be defined as not an ozone depleting substance.

The proposed **Act for a Healthy Massachusetts** requires the substitution of priority toxic chemical uses when safer alternatives are available. The draft bill delegates assessment responsibilities to Massachusetts’ TURI, which would be responsible for 1) working with the state’s science advisory board for toxics use reduction to determine criteria for what is safer and 2) evaluating the availability of safer alternatives (including the costs of the alternatives and their technical availability). After TURI completes a safer alternatives assessment for a chemical, the state’s Executive Office of Environmental Affairs would be responsible for developing a chemical action plan that requires users of the chemical “to act as expeditiously as possible to ensure substitution of the priority toxic substance with a safer alternative, while acting to minimize job loss and mitigate any other potential unintended negative impacts.” The state’s Department of Environmental Protection would be responsible for developing regulations for implementing the legislation.

In Europe, the new **REACH** legislation creates a new organization, the European Chemicals Agency, to implement the law as well as two new committees that consist of representatives from member states. The Committee for Risk Assessment is responsible for assessing the “risk to human health and/or the environment arising from the use(s) of the substance [of concern], including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives” (Article 64). And the Committee for Socio-economic Analysis is responsible for assessing the “socio-economic factors and the availability, suitability and technical feasibility of alternatives” to chemicals of concern (Article 64).

Table 2 lists the alternatives assessment requirements of RoHS, CAAA–Title VI, Act for a Healthy Massachusetts (proposed), and REACH. The requirements range from the minimalist Title VI — which only requires an assessment of hazards (is the alternative not an ozone depleting substance)

TABLE 2 **Scope of Alternatives Assessments Required in Legislation**

Assessments	RoHS	CAAA–Title VI	MA–AHM (proposed)	REACH
Hazard	X	X (not an ozone depleting substance)	X	X
Exposure	X		X	X
Risk				X
Economic			X	X
Technical Performance	X	X	X	X

Explanations: “X” = assessment requirement of the legislation; blank cell = not required by the legislation. Abbreviations: AHM = Act for a Healthy Massachusetts; CAAA = Clean Air Act Amendments of 1990; MA = Massachusetts; REACH = Registration, Evaluation and Authorisation of Chemicals; RoHS = Restriction of Hazardous Substances

and technical performance (availability of technically equivalent alternatives) — to REACH — which requires risk assessments (hazard and exposure), economics, and technical performance.* ***The requirements of an alternatives assessment — hazard, exposure, quantitative risk assessment, economic analysis, and/or technical performance — matter: the broader the scope of an alternatives assessment, the greater the demands on government resources and the greater the potential opportunities for laggard businesses to delay change.*** For example, Section 6 of the Toxic Substances Control Act requires that EPA evaluate policy options for each use of a chemical and select the “least burdensome regulation” when reducing the risks associated with that chemical. This creates a situation where it is challenging, if not impossible, for EPA to argue that availability of a safer, feasible alternative is sufficient rationale for strong restrictions on a chemical.

The straightforward approach to defining an alternative to a toxic chemical as safer is: the alternative does not pose the same type of hazards that led to the restriction of the toxic chemical in the first place. For example, a safer alternative to an ozone depleting substance is one that does not deplete the ozone layer. This is a more straightforward regulatory option than requiring that an alternative pose no significant adverse effects to human health or the environment. Requiring the latter will create greater delays in regulatory action as opponents of change highlight every single hazardous property associated with alternatives. The downside to a limited definition of “safer” is that chemicals with some adverse effects may be used as safer substitutes.

Technical Assistance:

“Technical assistance helps entities to make better environmental choices by clarifying the consequences of their actions and what techniques or equipment reduce those consequences. Technical

* The Massachusetts bill does not require a quantitative risk assessment, but rather a qualitative assessment of hazards and exposures.

assistance also may be focused on educating the general public about the environmental implications of existing and proposed programs and policies.” — U.S. Congress, Office of Technology Assessment (1995)²¹

“Drop in” chemical substitutes often do not exist and require changes in processes or manufacturing methods. Such changes may present a hindrance to substitution, particularly for small- and medium-sized companies which cannot risk a technology failure. Technical assistance programs can be effective means for transferring information about chemical hazards, exposure, and risks; analytic methods and tools; and technology availability, costs, and performance to businesses. Direct, on-site technical assistance provides small numbers of businesses with in-depth knowledge about pollution prevention techniques, while conferences, trainings, seminars, and business-to-business mentor/demonstration programs diffuse information to the broader business community. In Massachusetts, the combination of technical assistance, toxics use reduction (TUR) plans, reporting requirements, and use fees of TURA combined to reduce toxic byproduct generation by 30 percent and toxic chemical use by 20 percent between 1990 and 1995.²²

The TURI Surface Solutions Laboratory, which tests and evaluates the effectiveness of safer cleaning chemicals and related equipment, is an example of an innovative technical assistance project that provides direct research support to small businesses.²³ The TURI Lab facilitates technology transfer of safer and effective cleaning methods, servicing firms without the technical capacity to perform such research in-house. TURI estimates that the work of the laboratory has resulted in decreased consumption of organochlorinated solvents by over 100,000 pounds.²⁴

Technical assistance programs, relative to other environmental regulatory programs, involve moderate costs. Funding for the Massachusetts TUR program, for example, has averaged approximately \$5 million per year. For businesses, the costs of technical assistance programs are typically low. Some programs are paid for by taxpayers, while other programs are funded by dedicated fees on producers and uses of toxic chemicals. In Massachusetts, for example, the TURA program is funded by fees on large-quantity users of toxic chemicals, with fees pro-rated by the size of the business.

Public participation in technical assistance programs will vary depending on the policy and its implementation. TURI, for example, has a community outreach program, that provides grants to non-profit organizations and municipalities; education, training, and outreach on TUR; and resources to assist communities and individuals for implementing TUR.²⁵

The technology change that occurs from technical assistance programs is likely to be of moderate impact. Technical assistance programs are likely to affect those businesses that have the willingness to change but limited capacity. Firms that are reluctant to change, the environmental laggards, will not be moved to change by technical assistance programs.

Substitution and TUR Plans: TUR or pollution prevention (P2) plans are tools for companies to identify ways to reduce the use of toxic chemicals. In some states, such plans are required for businesses under law. Under the Massachusetts TURA, TUR is defined as encompassing six different TUR techniques: substitution, product redesign, production process redesign, production process modernization, improved operations and maintenance, and in-plant recycling. Under TURA, “substitution” is defined as chemical-to-chemical substitution. Since TURA passed in 1989, the definition of substitution has grown to encompass any technique — be it product redesign, production process change, as well as chemical-to-chemical replacement — that leads to the elimination of the use of a chemical. For the purposes here, substitution plans focus on eliminating chemical use while TUR plans focus on reducing chemical use (with substitution one option among others). Indeed, it may be possible to significantly reduce the use of a chemical or even eliminate it through a production process design change. In some cases, where a substance is the basis of the product (for example metal plating using copper), substitution may not be an option.

An innovative feature of the TURA law is the requirement that a company’s TUR plan must be certified by an independent third party, known as TUR Planners. This means that the plan a business submits to the state must meet a minimum level of content as required by regulation and of quality as certified by the planner. The TUR Planners have become champions for the implementation of TURA.²⁶

Substitution or TUR plans completed by businesses avoid the resource constraints of government-completed alternatives assessments. The best model of alternatives or substitution assessment planning is under the TURA, where large-quantity manufacturers and users of toxic chemicals are required to develop plans for reducing chemical use. Only summaries of the plans are submitted to the regulatory agencies though the full plans are accessible to them.

Substitution planning is now part of the recently passed European REACH legislation. REACH requires all manufacturers, importers, and downstream users applying for an authorization to “analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution” (Article 55). All firms producing, importing, or using a carcinogen, mutagen, reproductive toxicant, persistent, bioaccumulative and toxic chemical (PBT), or very persistent (vP) and very bioaccumulative (vB) chemical, and requesting an authorization for continued use will be required to complete a substitution plan.²⁷ The stated aim of all authorized chemicals is to “ensure that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.”²⁸

Chemicals which are PBT or vPvB may only be granted a use authorization if it is shown that the socio-economic benefits outweigh the risk to human health or the environment and if there are no suitable alternative substances or technologies (see Article 59(4) of REACH). As part of the process of reviewing authorization requests, interested third parties may submit “information on alternative substances or technologies” (see Article 63(2) of REACH). The time limit of ongoing use of a chemical will be decided on a case-by-case basis and the Commission can

call for a review of the use authorization if new information, such as on suitable alternatives, becomes available (see Article 60 of REACH).

Government resources for substitution/TUR planning are relatively low, with the work including the writing of regulations, educating businesses on compliance, enforcement, and providing public access to non-confidential data. Public participation in TUR planning in Massachusetts has been minimal, with representatives from NGOs participating in the initial framing discussions on TUR planning requirements. TUR planning, as noted in the preceding section on technical assistance, has been a key component in the success of the Massachusetts toxics use reduction program.

Chemical Restriction and Substitution:

- Chemical restriction policies prohibit the manufacture, use(s), and/or distribution of a chemical or chemicals.
- Chemical substitution policies require the replacement of hazardous chemicals with safer alternatives.

Chemical restriction and chemical substitution policies trigger the assessment, development, and use of alternatives to toxic chemicals. As such, they are powerful policy options for transforming the toxic chemical economy. Given their effectiveness in changing chemical use when successfully implemented, this section examines the differences and similarities between restriction and substitution policies, the scope of chemical restriction policies, how governments regulate industrial chemicals differently from other chemicals, and the core components of restriction and substitution policies.

On substitution and restriction policies. In their pure forms — in theory rather than practice — substitution policies explicitly link chemical displacement to an evaluation of the alternatives whereas restriction policies do not address the availability and risks associated with the alternatives. Substitution policies through substitution planning requirements (under Substitution and TUR Plans above and see also the section under Government-Sponsored Alternatives Assessment) bring the alternatives assessments of businesses into public light. Whereas under chemical restriction policies the assessment of alternatives occurs within the firm and the assessment process used, evaluation criteria considered, and alternatives evaluated and selected occur without any guidance from government or public accountability. The result may be the selection of an equally hazardous chemical (not subject to restrictions) or a chemical of high concern for another hazard endpoint (such as acute toxicity).

In practice, chemical restriction policies are more nuanced. While the process and criteria for selecting alternatives occurs largely outside the public sphere of chemical restriction policy, the availability of technically equivalent alternatives is invariably addressed through exemptions and the implementation process to ensure that chemical uses critical for public health, safety, or security are not removed from the market. Additionally many chemical restriction policies include provisions to evaluate the hazards of alternatives.

An alternative approach to restrictions (do not use) and substitutions (replace with safer alternative) is “authorizations.” An authorization is a right to use a chemical. Under authorizations chemical producers and/or users are not allowed to use a chemical until they apply for the right to use the chemical and their application is approved by a regulatory agency.

The scope of chemical restrictions ranges from narrow use restrictions to broad integrated chemical policy laws that empower regulatory authorities to evaluate and restrict a range of toxic chemicals (for example, REACH). Chemical use restrictions — policies that ban select uses of a chemical while allowing other uses to continue — are the most common types of restrictions and include:

- Mercury products legislation (adopted to various degrees in more than 20 states);
- Toxics in packaging legislation (enacted by 17 states);
- Cosmetics Directive (European Union);
- Restriction of Hazardous Substances (RoHS) in Electrical and Electronic Equipment Directive (European Union); and
- DecaBDE restrictions (Maine, Washington State, and Sweden).

Examples of restrictions on the manufacture of all uses of a chemical or class of chemicals are much less common than “use restrictions” — only individual use(s) of a chemical are prohibited. A notable example of a chemical phase-out is Title VI — Stratospheric Ozone Protection of the Clean Air Act Amendments of 1990, which was written to prohibit the production and use of many ozone depleting substances. Title VI states that it “shall be unlawful for any person to produce any amount of a class I substance” by 2002 (Sec. 604 (b)) and requires the U.S. EPA to phase out “production of class I substances” and to “insure that the consumption of class I substances in the United States is phased out and terminated” (Sec. 604 (c)). Reflecting the challenges of a complete phase-out of production and all uses of a chemical, Title VI includes exemptions for “essential uses” (medical devices and aviation safety — Sec. 604 (d)) and “national security” (Sec. 604 (f)).

Chemical restrictions and substitutions are effective in generating technology change. As Nicholas Ashford has found, stringent regulations (such as chemical restrictions and substitutions) are effective at generating technology innovations.²⁹ Confronted with the loss of a chemical, manufacturers and end users innovate to achieve the same function at a competitive price. Chemical restrictions and substitutions, however, are costly to the manufacturers whose chemical is restricted or displaced through substitution and require significant government resources to implement. Because chemical manufacturers do not want to lose products to regulation, they intensely resist restrictions and substitutions of their products, causing the costs of government implementation to rise.

Governments regulate the production, use, and distribution of industrial chemicals differently than pharmaceuticals, pesticides, and cosmetics. In the United States, for example:

- Pesticides are regulated under the Food, Drug, and Cosmetic Act (including Title IV— known as the Food Quality Protection Act of 1996) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA);

- Cosmetics and pharmaceuticals are regulated under the Food, Drug, and Cosmetic Act; and
- Industrial chemicals are regulated under TSCA.

The different regulatory structures for the production, use, and distribution of chemicals relate to the function of the chemicals and our knowledge of exposure to these chemicals. Pesticides are designed to be toxic and spread into the environment. Pharmaceuticals are designed to affect biological functions of humans. Cosmetics are applied directly to our bodies. Thus, the laws for pesticides and pharmaceuticals (and cosmetics in Europe, see below) have tended to be more stringent than for industrial chemicals.

The use of cosmetics, like industrial chemicals, is weakly regulated in the U.S. As summarized in an article published by the Food and Drug Administration (FDA):

The regulatory requirements governing the sale of cosmetics are not as stringent as those that apply to other FDA-regulated products. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, cosmetics and their ingredients are not required to undergo approval before they are sold to the public. Generally, FDA regulates these products after they have been released to the marketplace. This means that manufacturers may use any ingredient or raw material, except for color additives and a few prohibited substances, to market a product without a government review or approval.³⁰

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.

The **core components of chemical restriction and substitution policies** are:

- Identifying target chemicals.
- Assigning burden of proof.
- Defining the basis for restriction or substitution.

The identification of target chemicals involves defining the criteria for identifying target chemicals and defining who is responsible for creating the list of chemicals. In chemical restriction and substitution policies, the target chemicals are either identified by legislators in the writing of the law and/or by regulatory agencies on the basis of a process outlined in the law.

Legislators often specify either the chemicals that should be targeted for restriction/substitution or the classes of chemicals to be targeted. For example:

- The European Commission Cosmetics Directive of 2004 specifies classes of chemicals for restriction: category 1 or 2 carcinogens, mutagens, or reproductive toxicants shall not be used in cosmetic products.
- Title VI of the Clean Air Act Amendments of 1990 specifies that ozone depleting substances be phased-out with the schedule divided into class 1 and class 2 substances.
- The proposed Act for a Healthy Massachusetts specifies ten chemicals that are targets for substitution.

The classes of industrial chemicals governments have targeted for restriction are:

- Ozone depleting substances;
- Persistent and bioaccumulative and toxic to either aquatic organisms or humans (PBT);
- Very persistent and very bioaccumulative (vPvB); or
- Toxic to humans:
 - Carcinogenic;
 - Mutagenic (or genotoxic);
 - Reproductive or development toxicant;
 - Neurotoxicant; or
 - Endocrine disruptor.

REACH, for example, identifies chemicals with these hazardous qualities (except ozone depleting substances and neurotoxicants) as priorities for authorization (see Article 57).

Alternatively, legislators may delegate authority to a regulatory agency (or other government body) to identify target chemicals for restriction. For example, the proposed federal Child, Worker and Consumer Safe Chemicals Act delegates authority to the U.S. EPA to select 300 priority chemicals for restriction based upon a broad set of health parameters.

The burden of proof relates to who must demonstrate responsibility for showing that a chemical and its uses are harmful or safe; or alternatives are available, cost-competitive, and/or safer. Too often with industrial chemicals, the burden of proof rests with government to show that a chemical and its uses cause harm or are unsafe. Under the Food Quality and Protection Act (FQPA), for example, it is the responsibility of the U.S. EPA to set a “tolerance” for any pesticide residue in or on food. A “tolerance” is a safe level of exposure: “the term ‘safe’, with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue” (Sec. 408(b)(2)(A)(ii)).

The REACH legislation in the EU attempts to reverse part of the onus by requiring businesses to submit registrations for all existing chemicals (including demonstrating measures for safe use of the substance and “authorization” requests for the continued use of chemicals of high concern. The businesses must demonstrate that their chemicals are either “adequately controlled,” or that alternatives are not available or pose greater risks. But the EU is still responsible for confirming that chemicals of high concern are adequately controlled or, if not adequately controlled or if a PBT, that the socio-economic benefits outweigh the risks and availability of alternatives. Thus, even in an authorization process, where business must apply to use a chemical, the burden of proof on government is still significant.

Substitution policies, like the proposed Act for a Healthy Massachusetts, require significant government research into the availability, costs, hazards, and exposures related to alternatives. The EU REACH legislation has designed in greater responsibility for businesses by requiring the submission of substitution plans.

The standard for action is how legislation defines the legal authority of government to act, in this case, to restrict, substitute, or authorize chemical use. Examples include:

- TSCA: chemical use(s) must pose “unreasonable risk” and the U.S. EPA must apply the “least burdensome” regulation to reduce that risk.
- REACH has multiple standards for action:
 - “Authorization” — businesses must apply to use chemicals of high concern.
 - “Adequate control” — standard for approving authorization.
 - “Restriction” — separate process from authorization to prohibit chemical uses.
 - Alternatives assessment — business required to perform “an analysis of the alternatives” and submit a “substitution plan.”
- FQPA: “determination of safety” as defined by “reasonable certainty that no harm will result from aggregate exposure.”
- Clean Air Act Amendments of 1990 — Title VI: “phase-out production and consumption” of ozone depleting substances.
- The proposed Act for a Healthy Massachusetts: “safer alternatives.” If safer alternatives exist, as determined by TURI, then the state is justified in taking action.

Standards for action in chemicals policy are founded upon different types of assessments: hazard, exposure, risk, and/or substitution assessments. Quantitative risk assessments (hazard and exposure) are at the heart of TSCA, REACH, and FQPA. Hazard assessments are the basis of action for Title VI of the Clean Air Act Amendments of 1990, Cosmetics Directive, and RoHS Directive. Substitution assessment is the driving method behind action in the Act for a Healthy Massachusetts. Table 3 lists each of these methods, describes their justification for regulatory action, and the advantages and challenges to implementation.

TABLE 3 Chemical Assessment Methods for Justifying Regulatory Action

Assessment Method	Justification for Action	Advantage(s)	Challenge(s)
Hazard	<p>Act if a chemical is identified as a hazard of high concern.</p> <p>For example, if a chemical is determined to be a carcinogen, then restrict the chemical without assessing exposures and quantifying risks.</p>	Inherent properties of a chemical are sufficient for action. Most effective means for reducing risk is to reduce hazard (rather than exposure). Acting on hazards is analogous to pollution prevention: best method to reduce risks is to prevent rather than control pollution.	Defining criteria for listing chemical as a hazard. For example, are adverse reproductive effects at very high doses in animal studies relevant for listing a chemical as a reproductive toxicant?
Risk	<p>Act if a chemical use poses adverse effects above a defined level of acceptable risk.</p> <p>Being identified as a carcinogen is not sufficient for taking action, need to assess whether use of the carcinogen will result in risks above some threshold, such as greater than a cancer risk of 1 in 1 million.</p>	Known and developed process for quantifying risks. Used by U.S. EPA and EU to regulate chemicals.	More time intensive and subject to greater number of assumptions and uncertainties than hazard assessment.
Substitution	<p>Act if a safer alternative is available.</p> <p>Critical to substitution is defining what is safer. For example, a safer alternative is not a PBT, vPvB, CMR, or endpoint of equivalent concern.</p>	Promotes development, evaluation, and use of alternatives. Used by businesses moving away from hazardous chemicals.	Defining the criteria by which “safer” is defined. Potential for paralysis by analysis if all alternatives must go through risk assessment process.

DEFINING SAFER ALTERNATIVES

An explicit aspect of the substitution principle and alternatives assessment is that it will lead to the selection of a safer alternative. However, in the field of hazardous chemicals management, the decision to remove a highly hazardous chemical due to either government or company policy often lacks an accompanying assessment of whether the alternative is indeed safer and for whom (for example, a substance that is safer for the environment may be a greater hazard to workers). This section identifies the substitution strategies available to businesses and begins the discussion of how to define a safer alternative.

When identifying and selecting alternatives to chemicals of high concern,* businesses can select from a handful of substitution strategies. Table 4 defines six substitution strategies commonly employed by businesses when selecting alternatives: chemical substitution, mechanical/process substitution, material substitution, product redesign, system change, and discontinue activity.

TABLE 4 **Substitution Strategies: Definitions and Examples**

Substitution Strategy	Definition	Example
1. Chemical Substitution	Select alternative chemical.	Chemical use: DecaBDE flame retardant in TVs. Chemical substitution: Replace decaBDE with a different chemical flame retardant, for example, resorcinol diphenylphosphate.
2. Mechanical or Process Substitution	Select mechanical solution.	Chemical use: Chlorine dioxide in wood pulping. Mechanical substitution: Replace the chemical pulping process (which uses chlorine dioxide) with a mechanical pulping process.
3. Material Substitution	Select a different material (that does not require the function of the chemical of high concern).	Chemical use: Diethylhexyl phthalate (DEHP) use as a plasticizer in polyvinyl chloride (PVC) intravenous bags Material substitution: Avoid DEHP by selecting non-PVC plastics that do not require the addition of plasticizers and, thus do not contain DEHP.
4. Product Redesign	Change product design or select alternative product.	Chemical use: Flame retardants in foam chair cushions. Product redesign: Redesign chair to eliminate the foam (the fuel source that must be flame retarded), thus eliminating the need for a flame retardant.
5. System Change	Change production or service system to eliminate the need for the product (containing the chemical of high concern).	Chemical use: Pesticides, for example, atrazine. System change: Organic farming: change farming practices, including crop selection and rotation, to eliminate need for pesticides.
6. Discontinue Activity	Stop the activity that requires the use of a chemical of high concern.	Chemical use: Incorporation of antimicrobial agents into textile products. Discontinue activity: Determine that the use of antimicrobial agents in textiles is unnecessary to product performance and stop using them.

* Steps #4 and #7 in the Alternatives Assessment process: Step #4 is identify alternatives to chemicals of high concern and Step #7 is select preferred alternative. See Section 1 for an overview of the Alternatives Assessment process.

A challenge with most substitution strategies—excepting system change and discontinue activity—is determining whether the alternative selected is safer than the chemical of high concern. In substitution strategy #6, discontinue activity, the alternative is clearly safer: end the use of the chemical of high concern. However, for many situations, discontinue activity is not an option. In substitution strategy #5, system change, the opportunity for creating a safer alternative (to the chemical of high concern) is significant because it requires changing multiple elements of the product or service system. System change, as in the example of organic farming, requires changes to all elements of farming, creating the opportunity for optimizing environmental performance across the whole practice of farming.

For substitution strategies #1–#4, the challenge is defining and determining whether the alternative is safer and, very importantly, creating an analytic process that is reasonable to complete. It is beyond the scope of this module to define frameworks for specifying whether an alternative material or product is safer than the chemical of high concern. Rather the approach here is to address a few of the challenges of substitution, including:

- Definition of safer alternative;
- Data availability and quality concerns; and
- Trade-offs.

What a safer alternative is will depend on the definition of the term. For example, a “safer alternative” to a toxic chemical could be defined as:

- a) A functionally equivalent option, including a substitute chemical or material, or a redesigned product or process, that could be manufactured or used in lieu of the chemical of high concern; and
- b) Not being of high concern for:
 - i) Persistence and bioaccumulation and toxicity (PBTs);
 - ii) Carcinogenicity;
 - iii) Mutagenicity;
 - iv) Reproductive or developmental toxicity;
 - v) Neurotoxicity;
 - vi) Endocrine disruption; or
 - vii) Equivalent concern; or
- c) Not being of:
 - i) Very high concern for persistence and high concern for toxicity (vPT);
 - ii) Very high concern for bioaccumulation and high concern for toxicity (vBT); or
- d) Not having any breakdown products (metabolites or degradation products) or combustion byproducts that meet the issues of concern listed in (b) or (c).

Evaluating whether a chemical substitute is safer, based upon these criteria, is often limited by the lack of hazard data. Thus, language would have to be developed to state what type and quality of data would be sufficient for stating, “At this time, the available data suggests that the alternative is safer.” For example, would structure activity relationship data be sufficient for making that determination (when laboratory data are missing)?

In addition, it must be acknowledged that the above definition of “safer alternative” is not comprehensive — it does not address every single environmental or human health issue. Missing, for example, are other toxicological effects (for example, immune system effects or acute toxicity), water use, energy use, ergonomic concerns, and so forth. The limited scope of the definition of safer is done on purpose in order to a) help prioritize hazard endpoints of concern (resources are lacking to address every hazard endpoint at once) and b) create a framework that assists (rather than paralyzes) decision-making.

The scope of the definition of safer alternative needs to be manageable, otherwise no decision will be made as every alternative has its down side. For this reason it is critical to recognize that a safer alternative is a dynamic rather than a static solution. This means that while an alternative may be safer by the above definition of “safer alternative,” it is very likely that the solution has other significant down sides, such as energy use or process changes that could result in ergonomic strain that will need to be improved upon over time. Safer alternatives are context dependent, and as the analytic framework expands the “safer” alternatives will change. Thus, the concept of continuous improvement needs to be integrally connected with safer alternatives. In this framing of safer alternatives as subject to continuous improvement over time, what some may deem as a trade-off in substitution — for example, toxics reduction versus increased energy consumption — is only a temporary situation that must be improved over time; unintended consequences of substitution need to be identified, flagged and addressed as quickly as possible. Toxics reduction is the first but not only step in addressing the problems of highly hazardous chemicals. Substitution processes need to include thoughtful consideration (though not exhaustive) of the reasonable potential risk trade-offs that might occur (between workers, communities, and environment or throughout a chemical/product lifecycle), and process changes that might be needed for successful implementation. Such considerations should not hold up efforts to undertake substitution, however.

The policy implications of the challenges of alternatives are:

- Clearly defining safer alternative;
- Articulating data availability and quality needs (for an alternative to be deemed, “safer”); and
- Integrating consideration of the reasonable potential trade-offs of the alternatives and continuous improvement into the concept of safer alternatives.

CONCLUSION

Table 5 summarizes the outcomes for the policy options included in the sections above called Alternatives Selection Policies and Policies that Support Multiple Steps in an Alternatives Assessment, as they are especially critical to the selection of safer alternatives by chemical producers and users. The outcomes included in Table 5 are effects on cost, business practice, public participation, and technology change. The most effective policy options for changing technology are chemical

restrictions and chemical substitutions. Yet these options are highly contentious and pose high costs for businesses and government. The costs of chemical restrictions are heavily borne by the chemical manufacturers, but will vary for chemical users depending on the availability of alternatives and the extent to which they have already changed their chemical use.

Technical assistance, planning requirements, government procurement, and eco-labels all involve moderate costs to business or government and result in moderate effects. These policy options will not drive change among laggard businesses, but will support change among businesses that lack the resources and focus needed to transition to safer alternatives (technical assistance and planning) or that need deeper market incentives to change (government procurement and eco-labels).

Alternative assessments as a stand-alone policy option will not be effective in bringing about technology change. Their value is in being linked to the other policy options.

Public participation is poorly served by all of the policy options included in Table 5. That's because the dialogue involved in the development and implementation of these policies is technical. Engaging the wider public outside of environmental organizations with technical expertise will require different policies that focus on right-to-know, goal-setting, and evaluating progress towards achieving goals.

Widespread success in substitution will require a package of policy initiatives that support each of the steps in an alternatives assessment process. To date, there are a handful of success stories among business innovators in implementing substitution. But for these successes to spread to the entire American business community will require government action. Without support for each step in the alternatives assessment process, businesses will lack the data on chemical use and hazards, incentives for and availability of safer alternatives, and the capacity to evaluate alternatives.

Government can help chemical users by evaluating hazards of chemicals, classifying chemicals into levels of concern (high, moderate, low, or unknown), identifying and restricting chemicals of high concern, and listing alternatives. Businesses that use chemicals of high concern should be required to perform substitution plans.

Government needs to play an active leadership role in promoting the development and diffusion of safer substitutes through programs that promote green chemistry and the development of safer alternatives.

TABLE 5 Assessment of Policy Options for Substitution and Alternatives Assessment

Outcomes	Analysis— Alternative Assessments by Government	Technical Assistance— Clearinghouses, On-site Support, etc.	Require Planning— Substitution Plans by Business	Require Business Action— Chemical Restrictions or Substitution	Procurement —Government Environmentally Preferable Purchasing
Cost					
Chemical Manufacturers	Low	Low	Moderate	High	Low
Chemical End Users	Low	Low	Moderate	Depends	Low
Government	High	Moderate	Low	High	Moderate
Business Practice & Public Participation					
Action Forcing	Low	Low	Moderate	High	Moderate
Gives Prevention an Advantage	High	Moderate	High	High	High
Focuses on Learning	High	High	High	High	Moderate
Public Participation	Low–Moderate	Low–Moderate	Low	Low	Low–Moderate
Change In Technology					
Chemical Manufacturers	Low	Moderate	Moderate	High	Low–Moderate
Chemical End Users	Low	Moderate	Moderate	High	Moderate
Overall Assessment	High Government Cost & Low Technology Change	Moderate Government Cost & Moderate Technology Change	Moderate Business Cost & Moderate Technology Change	High Cost & High Technology Change	Moderate Cost & Moderate Technology Change

All too often the debates over any toxic chemical involve only the government, manufacturers of that chemical, and occasionally, environmental groups. Absent from these deliberations are manufacturers of the alternatives or downstream users who are interested in the safer alternatives. **Creating policy mechanisms that increase incentives for businesses that produce or want safer alternatives and for the public to participate in implementation will be critical to the success of chemical policy legislation.** But the public will lose interest once experts start squabbling over degrees of hazard, levels of exposure, and costs of alternatives. What the public wants are safer alternatives. Thus, an important mechanism of chemical policy is the setting of goals and the benchmarking of progress towards those goals. The public is interested in the goals and can demand progress towards achieving them.

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MODULE 5

Policy Options for Chemical Innovation and Green Chemistry

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McPHERSON

What are the characteristics of innovation in the chemicals industry and how can we support and develop green chemistry?

The future will put new pressure on chemistry and the chemical industry to invent and develop safer and more sustainable chemicals. Not only is the public increasingly sensitive to the risks of conventional chemicals, but national and international governments are increasing scrutiny and tightening regulations on many of the chemicals of highest concern. Greater attention to chemicals that pose significant health and environmental risks and the prospect of further government regulations provide incentives for chemists and private chemical research labs to direct research towards safer chemical substitutes. Indeed, this increasingly sensitive context has encouraged some firms within the industry to reformulate chemical process steps and redesign chemical products in order to substitute more environmentally friendly chemicals for hazardous chemicals used in chemical synthesis or final products. Today, there is a small, but growing “green chemistry” movement among chemists and private firms that conduct research on new chemistries to design chemicals and chemical synthesis and processing procedures that avoid hazardous substances and more self-consciously protect the environment and human health.

CHEMICAL INDUSTRY AND INNOVATION

However, the current state of the chemical industry is not conducive to innovation inspired by environmental or health factors. The current efforts to introduce green chemistry or other innovations that conserve resources and reduce wastes are slow, piecemeal, and often overtly resisted. The bulk chemical industry is a mature, capital intensive, concentrated, multinational industry. The specialty chemical industry is highly fragmented with significant diversity among chemical products and firms. Process innovation is often risky, expensive, and difficult, giving the chemical industry one of the longest new product technology cycles (10–20 years) and new process technology cycles (40–50 years) in all of manufacturing.¹ Many of the industry’s fundamental technologies and manufacturing procedures (for example, methanol/ethylene/propylene/benzene/toluene/xylene, /and chlor-alkali) were developed and “locked in” decades ago, creating technology improvement pathways that embrace incremental changes and resist fundamental transformations.²

Because the customers of the chemical industry tend to be chemical formulators and product manufacturers rather than product consumers, market signals from final users of chemical products have little impact on the industry. Indeed, government agencies charged with regulating the industry and its products tend to be focused on and overwhelmed by risk management activities, rather than industrial development and, therefore, do little to promote innovation directly. Add to this a long history of industry trade associations resisting government intervention, countering and subverting critical scientific studies of adverse chemical effects, and employing unrelenting political pressure to protect current investments and the result is an industry with a very narrow and skeptical attitude towards innovation driven by factors other than market advantage.

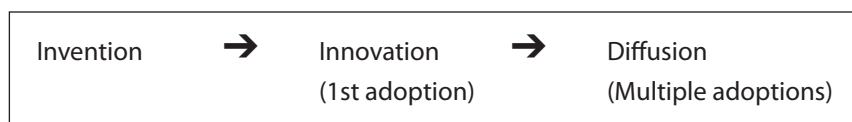
If the chemical industry is to embrace innovation driven by a vision of a clean and safe environment, it will require new government policies and new public demands that reach deeply into the technological and financial decision-making structures of the industry. Green chemistry offers a promising vision, however, it must avoid becoming simply a clever way to reduce costs or a fancy way to create a public image. True innovation means a fundamental re-thinking of the industry's source materials, processing technologies, and commercial products and it will require more than a patient reliance on market forces alone.

The objective of this module is to consider the conditions that lead to innovation in the chemical industry and to propose a set of policy options for governments that are seeking to encourage green chemistry and environmentally sensitive innovations.

CONVENTIONAL DRIVERS FOR CHEMICAL INNOVATION

Chemists in academic chemistry labs, government research centers, and private firms are often engaged in generating new chemicals. Most never go beyond the laboratory or point of conception. The term conventionally used for this is *invention*. Scientists are involved in inventing new chemicals, often with the hope of commercial applications. The term *innovation* is traditionally used to indicate the adoption of a chemical or chemical process into a commercial or practical application. Thus, innovation involves the adoption of inventions. The first successful *adoption* of a new chemical into a process is considered the first innovation, although innovation can occur at later times whenever a potential user converts to a new chemical or process. Diffusion involves multiple adoptions of an innovation. See Figure 1.

FIGURE 1 **The Process of Innovation**



There is a broad library of business literature on invention and innovation with much attention paid to the conditions or processes that lead a firm to innovate and the effects that innovation has on market and corporate practices. Joseph Schumpeter argued that innovation benefits a firm by offering temporary monopoly control over a new product and, thereby, permits the firm to gain an enhanced position in the market. Michael Porter sees technical innovation as one means by which a firm can differentiate its products from those of its competitors either by lowering costs, shifting costs, creating a “first mover advantage,” or shifting the structure of the industry to its advantage. James Utterback differentiates product from process innovation, but sees them as interdependent in any major industrial transformation. He notes that technical innovations tend to go through three phases starting with new “pioneer” product commercialization, followed by a transitional phase in which there are many product variations and process changes among many competitors, and, finally, a concluding phase where the market is narrowed down to a few competitors who focus primarily on minor product or process refinements.³

Much of the business literature is focused on corporate innovation for commercial benefits — expanding market share, increasing profits — however, there is also a broad behavioral science literature on the social dynamics of innovation. While the social science scholarship on innovation can be traced back to the early twentieth century, much of the new literature has developed from the work Everett Rogers published in *Diffusion of Innovations* in 1962.⁴ Rogers recognized the diffusion of innovations as a social pattern similar to the way an infection spreads through a population: there are a few early innovators (leaders), many mid-term innovators who follow a successful trend, and some (laggards) who hold out against an innovation for many years. If adoptions of an innovation are plotted across a time line, the number of adopters tend to follow a bell curve rising from a few to many and back to a few over the time period.

Rogers examined many cases of innovation and noted that the general pattern was affected by certain attributes of the product or behavior that was being adopted. Specifically, he identified five characteristics of innovations that affected their success (rate of adoption). They include:

- Relative advantage.** Improvement of an innovation over current practices.
- Comparability.** Consistency of an innovation with existing needs.
- Complexity.** Assessment of difficulty in understanding or using an innovation.
- Trialability.** Degree to which an innovation can be tried out before full adoption.
- Observability.** Degree to which the advantages of an innovation are observable by others.

Innovation in the chemical industry follows similar characteristics. New chemicals or chemical processes must provide functional or cost advantages to be considered seriously. The sophistication of chemistry, today, means that chemical synthesis or process changes are regularly modeled through computer simulations before being piloted. This fact provides a significant amount of information that can be used to explicate potential conversions and reduce uncertainty. Bench-scale experiments are typically scaled up to pilot plant or beta tests prior to adoption in order to assess performance characteristics and identify unanticipated side effects. These lab experiments

and pilot processes are useful for demonstrating possibilities and convincing skeptics that an innovation will be successful. However, most innovation in the large, bulk chemical companies remains incremental — adjustments to otherwise fixed investments — while more fundamental “breakthrough” innovation is the province of the smaller, less highly capitalized firms.⁵

The introduction of a chemical innovation in the lifecycle of a chemical or product can occur at different points and involve different actors, including:

Chemical inventor. Academic and corporate research laboratories turn out thousands of new chemicals each year.

Chemical manufacturers. Chemical manufacturers can develop new synthetic routes for making chemicals or new chemicals to substitute for chemicals currently on the market.

Chemical processors. Firms that process raw chemical feedstocks into marketable chemical products can adopt new processing procedures, adopt new chemical processing intermediaries, or create new chemical products.

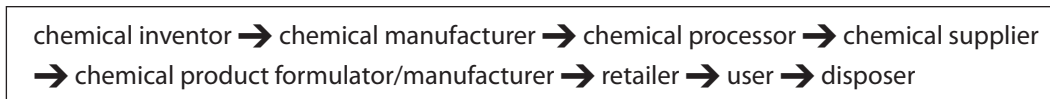
Chemical suppliers (vendors, distributors). Chemical suppliers can adopt a new chemical product and market it as a substitute for chemical products currently on the market.

Chemical product formulators or manufacturers. Commercial product formulators or manufacturers can adopt new chemical intermediaries to use in manufacturing or new chemical products as constituents of finished commercial products.

Chemical product retailers. Retailers can specify or selectively purchase preferred products to direct innovation.

Users. Users can drive innovation through selective purchasing. (See Figure 2)

FIGURE 2 **The Chemical Product Supply Chain**



The incentive to innovate can be stimulated at any point in the linear relationship (the so-called “supply chain”) of these actors. Downstream chemical users may seek a new chemical product from processors or manufacturers or upstream manufacturers may introduce a new line of chemicals and work to get downstream user acceptance. Sometimes one actor may adopt an innovation alone, however, achieving a successful adoption often requires a cooperative relationship among actors willing to accept an innovation and its consequences. For instance, a chemical supplier may work with formulators to develop a new chemical product or a chemical processor may collaborate with manufacturers to introduce a new chemical into the market

There are many drivers that motivate firms to adopt new chemicals, new chemical products, or new chemical synthesis or processing procedures. They include conventional business factors, such as:

Performance. The functional characteristics of chemicals are a central factor in chemical selection. Chemical users seek chemical feedstocks and process intermediaries that meet desired product objectives and achieve optimal processing and manufacturing characteristics. Vendors and chemical suppliers often play an important role here by marketing new chemicals and chemical processes that promote higher product or process functionality. In addition, sophisticated customers may drive innovations by specifying specific product or process performance characteristics.

Costs. The drive to lower product or production processes by redesigning process chemistries or reformulating products compels firms to seek lower cost feedstocks and source chemicals. Vendors also play an important function here, often marketing new, lower cost chemicals that can replace higher cost conventional chemistries.

Competition. Few drivers are as potent as the innovations of competitors. Firms with large market shares are particularly attentive to changes in the chemical composition of competitor's products. Careful attention to the commercial media, information provided by chemical suppliers or information gathered through informal channels can be augmented by contracted consultants and reverse engineering investigations to learn about competitors' innovations.

Liability. Concern over future liability can also drive firms to move away from chemicals of known, or even suspected, hazard. The decision, by the 3-M corporation to withdraw and reformulate a highly successful product, Scotchguard, from the market in 1997 was driven by concern over potential liability when one of the constituents, perfluorooctanoic acid, was found as a contaminant in public body burden studies.

In addition, there are drivers based on information, such as:

New risk information. Scientific studies by academic laboratories or government agencies regularly provide new information on the hazards of chemicals in commercial use. New information on chemical exposures from occupational or environmental health studies, from human bio-monitoring, from wildlife studies, or from dramatic media stories can motivate a firm to re-examine its use of a targeted substance and seek its replacement. New information on the hazardous properties of currently used chemicals may encourage a firm to change chemistries in order to improve product safety, working conditions, or environment emissions. New information on the safety of alternative chemicals also can be a factor in driving chemical substitution or product redesign.

Public attention. An increasingly informed and concerned public has led to increased public attention to the risks of chemicals in products. Product manufacturers, particularly those who manufacture products used by sensitive populations (children, health conscious consumers), have grown quite sensitive to public information on chemicals. This development has led firms to substitute for chemicals that appear of growing public concern, even without specific customer attention.

Customer demand. As the public becomes more attentive to the risks of chemicals, customers may become more specific in specifying chemical constituents of products. Research by Eric von Hippel found that both downstream customers and distributors can play a significant role in driving innovations.⁶ Large product buyers such as the military or large equipment manufacturers (for example, the auto or aircraft industry) provide detailed specifications on chemical constituents. Recently large retailers such as Wal-Mart and Target, as well as hospital group purchasing organizations and many state and local government procurement offices, have become quite discerning in specifying chemical constituents in products.

There also are regulatory drivers, such as:

Government regulation. Governments can use statutes or regulations to phase out the use of specific chemicals. For instance, the European Union's Restriction on Hazardous Substances Directive's prohibitions on the use of lead in electronic products has led to rapid innovation in lead-free soldering and flame retardants. However, changes in government workplace exposure regulations or environmental release regulations that restrict the use of certain substances can result in process innovations, as well. Michael Porter and Class van der Linde argue that environmental and health regulations can guide firms towards lower cost production technologies that otherwise may not be identified by conventional management planning. Nicholas Ashford and George Heaton found that regulations can be primary drivers for promoting chemical research and innovation. From a review of the effects of several environmental regulations on corporate performance, they claim that regulation is most effective at motivating innovation if the regulations are clear and stringent and include a reasonable timeline for implementation.⁷

Government regulations on waste treatment that raise the cost of treating or disposing of specific chemical wastes can become drivers for chemical substitutions in production processes. Simple efforts by governments to list chemicals (such as the Swedish "Observation List") or target specific substances for research can draw industry attention to chemicals of concern and signal a search for substitutes even when such efforts precede government regulatory actions by many years. Indeed, James Clark of the University of York now sees government legislation as a more significant driver of chemicals innovation than process economics.⁸

Market standards. There are several private, professional and trade standard-setting bodies that can affect chemical selection decisions by creating market standards that prohibit or restrict the use of specific chemicals in particular applications. For instance, changes in flammability standards put forward by the American Society for Testing and Materials (ASTM International) can drive out specific flammable chemicals. Organizations such as the International Standards Organization or the American National Standards Institute regularly set and upgrade product standards and product testing procedures. In addition, various industry or private Codes of Conduct can specify practices that result in chemical innovation.

Even with such a battery of drivers for promoting chemical and process change, fundamental innovation in the chemical industry is relatively slow. Therefore, without more aggressive public or private policies, the transition to more environmentally sensitive chemicals and chemical processes is bound to be gradual and incremental.

ENVIRONMENTALLY MOTIVATED INNOVATION AND GREEN CHEMISTRY

Innovation towards more environmentally appropriate chemicals can occur either through selecting an existing chemical or chemical process with better characteristics and substituting it for a chemical of concern or by promoting the invention of a new chemical or chemical process. Selecting existing chemicals for substitution is covered in another module in this report. This module focuses on the development of new chemical products or processes.

Chemists have considered the natural environment in inventing new chemicals. It is said that Leon Baekeland was modeling natural chemistries when he invented the phenol formaldehyde polymer that became the first commercially developed plastic. Indeed, recognition of the environmental effects of the chemical pollution caused by the distillation of coal and oil was one of the drivers for recovering the by-products that became the basis for organic chemistry.⁹

Many improvements in the health or environmental characteristics of a chemical product or process have come about through simple incremental efforts to add a blocking configuration or remove a hazardous input. Indeed, the adoption of chlorofluorocarbons as refrigerants during the 1940s and 1950s was driven by a desire to reduce the flammability of the solvents and spirits conventionally used in compressors.

However, the recent efforts to use knowledge about environmental and biological processes to design and develop more environmentally friendly chemicals and chemical processes has opened a rapidly developing new specialty in chemistry often referred to as environmentally benign chemical synthesis, or “green chemistry.” Green chemistry does not focus on incremental substance substitutions; instead, green chemistry focuses on developing alternative chemistries that can be introduced throughout the entire process of chemical manufacturing. Paul Anastas and John Warner, two of the founders of the field of green chemistry, have defined the term green chemistry to mean “the utilization of a set of principles that reduces or eliminates the use or generation of hazardous substances in the design, manufacture and application of chemical products.”¹⁰

Green chemistry fosters research on alternative feedstocks and intermediaries, environmentally benign solvents, reagents, and catalysts, aqueous processing, and safer and more readily recyclable chemical products. Additional research focuses on alternative reagents and catalysts. It involves identifying catalysts that function in chemical transformations with minimal environmental harm (for example, minimizes energy inputs, maximizes yield, minimizes waste outputs, generates the least occupational exposure and the least accident potential).¹¹

Several firms within the pharmaceutical industry, such as Merck, Pfizer, Bayer, and GlaxoSmithKline, have taken leadership positions in promoting green chemistry. Because drug development is so research intensive and the health care industry is so sensitive to health objectives, these firms have found competitive benefits in promoting their green chemistry initiatives.¹²

The substitution of new chemical sources for petroleum in the petrochemical industries provides an innovation pathway parallel to green chemistry. Bioprocessing and bio-based chemicals provide a good example. The rising price of petroleum has reactivated research into the development of chemicals made from agricultural feedstocks. More than 15 percent of the dyes and 16 percent of the inks on the market are made from plant matter, as are several pigments, detergents, surfactants, and adhesives. There is a rapidly growing market for biopolymers-plastics made from corn, potatoes, sugar beets, or sugar cane. Cargill has a mill in Nebraska that can produce some 300 million tons of poly lactic acid per year from up to 40,000 bushels of locally grown corn. Their product, *NatureWorks*, is commercially available in various applications such as fibers, films, and extruded and thermoformed containers for packaging. However, biopolymers are not the only new area for green chemistry product development. Biorefineries, initially built to produce ethanol as a fuel, are rapidly being considered as a source for chemicals such as epichlorohydrin, glycerol carbonate, and succinic acid.¹³

There is some government program support for the development of green chemistry and bio-based materials. The U.S. Farm Bill of 2002 created a special research center for alternative uses of agricultural crops that is housed in the Department of Agriculture. The U.S. Environmental Protection Agency (US EPA) supports a small research program on green chemistry and there is a Presidential Green Chemistry Challenge that offers annual awards for individuals or firms that have demonstrated leadership in research or application of green chemistry principles. Over the last several years, this awards program has recognized Bayer's environmentally friendly synthesis of biodegradable chelating agents, PPG Industry's use of yttrium as a substitute for lead in cationic electro-coatings, and Rohm and Hass's design of an environmentally safe marine antifouling coating to replace tributyltin oxides.¹⁴

The American Chemical Society has created a separate non-profit entity, the Green Chemistry Institute, which promotes environmentally friendly chemistry through research, education, and conferences. The Institute and the American Chemical Society have developed secondary and higher education programs and curricula for training students in green chemistry. The Institute is the primary sponsor for a national Green Chemistry and Green Engineering Conference that is held annually in Washington in conjunction with the Presidential awards program.

Outside the United States, the European Union (EU) established a large research and technology platform called SusChem that focuses on industrial biotechnology, sustainable materials, and green reaction and process design. Japan, Brazil, China, and several African countries have established research programs for non-food materials made from agricultural feedstocks. In India, the government minister of science and technology has decreed that every college chemistry student

must take a year of green chemistry courses. Today, there are some 23 green chemistry centers in countries around the world.

BARRIERS TO THE DEVELOPMENT OF GREEN CHEMISTRY AND BIO-BASED CHEMICALS

Innovation is not always easily accepted. Innovation in the market typically advances some technologies and some firms while others lose out. Investments, jobs, and careers can be at risk. Potential losers can create stiff government and market barriers. Process innovations often are resisted because the immediate costs of production changes can be very high and the payback period long. Innovation in science can be fiercely resisted by those dedicated to the principles of what Thomas Kuhn called “normal science.”¹⁵

The development of green chemistry and bio-based materials has already encountered barriers. The advancement of green chemistry is currently being delayed by the lack of government funding and by the overt resistance of mainstream academic chemistry departments. While hundreds of millions of dollars of federal funds go to research into nanotechnologies and nano-scaled materials in the United States, a bill to fund green chemistry research for tens of millions of dollars has languished in Congress for the last four years. Pharmaceutical corporations have made investments in green chemistry research, but most industry sectors have not.

Although some higher education chemistry departments have proudly introduced green chemistry courses, only one green chemistry doctoral program exists in the country and the academic accrediting association has done little to embrace the concept. Indeed, some already see an insidious initiative to dilute and make meaningless the green chemistry definition. For instance, Dow Chemical has recently offered significant funding to one major university chemistry department to set up a “sustainable chemistry” program that avoids the accepted green chemistry definition in favor of a much looser and all-inclusive definition.

The development of bio-based chemicals has no easier road to cover. The earlier “chemurgy movement” of the 1930s and 1940s, which promoted agriculture-based chemicals such as corn- and soy-based solvents, adhesives, polymers, and fuels, was eviscerated following the close of World War II as the price of oil dropped and government subsidies evaporated.¹⁶ Today, the fledgling bio-fuel and biopolymer initiatives are already facing criticism as the cause of rising food and forage costs. Indeed, recent projections on the land and energy requirements needed for agricultural-based materials and recognition of the unsustainable nature of conventional industrial agriculture are currently casting a cloud of skepticism over bio-based chemicals.

FACILITATING INNOVATION IN GREEN CHEMICAL AND BIO-BASED MATERIALS

Governments have a range of policy tools that can be employed to promote innovation in the chemical industry. Some, such as the development of research programs, can support the invention of new chemicals or chemical processes, while others, such as regulatory restrictions, can encourage the adoption of alternatives, once invented. The first is an example of a “push policy,” because it promotes the expansion of innovation alternatives, while the latter is an example of a “pull policy,” because it creates an opportunity for the adoption of an innovation. These two types of policies often need to go hand in hand, because a pull policy cannot succeed if there is no invention to adopt.

While there are many incentives to design, develop, or adopt green chemistry alternatives, incentives often are not enough to make an innovation occur. Firms may require additional capital to purchase or adapt equipment, funds and time to implement conversions, workforce training to develop new skills, and new marketing strategies to convince customers to accept product changes. Governments can also help firms to overcome these barriers through a third kind of “facilitation policy” that provides funding, information, education, and technical support.

In addition, it is not always clear that an alternative chemical or chemical process is superior in terms of a complete set of environmental or health criteria. The aqueous cleaner used to replace a hydrocarbon-based cleaner, for example, may require more manual handling and may need ovens for drying products both of which present occupational risks. Indeed, efforts to manufacture chemicals from agricultural feedstock, may avoid the hazards associated with petroleum only to introduce the hazards of petroleum-based fertilizers, pesticides, and fuels and problems of soil depletion and water consumption associated with industrial agriculture.

To assist firms seeking to design and develop safer or cleaner chemicals, various decision-assisting protocols have been developed to help decision-makers assess the benefits and risks of potential substitutes (see Tickner, Module 3). Some of these tools are designed to simply display the hazards associated with potential alternatives while others actually allow users to screen alternatives based on decision rules built into the protocol.¹⁷

The German Institute for Occupational Safety has developed a hazard array protocol called the Column Model. This tool uses columns for each potential alternative to display hazard data on acute and chronic human health hazards, environmental hazards, fire and explosion hazards, and exposure potential. Similar tools have been developed by the Massachusetts Toxics Use Reduction Institute (“Pollution Prevention Options Analysis Systems”), Clean Production Action (“GreenScreen”) and the Zero Waste Alliance in Oregon (“Chemical Assessment and Ranking System”). These tools are useful in designing new chemicals or chemical processes because they provide health and environmental effects information on potential alternatives in a comparative data presentation.

Perhaps less helpful in making design decisions are the screening protocols because these tools rate information and conflate it into numeric or color-coded results. Examples include the Quick Scan approach developed by the Dutch Ministry of Housing, Spatial Planning and Environment and the Swedish Chemicals Inspectorate's PRIO for Risk Reduction of Chemicals.

The U.S. EPA Office of Pollution Prevention and Toxics (OPPT) has developed tools for encouraging green chemistry considerations in the development of new chemicals. For instance, the New Chemicals program has developed a computer-based program called the "Green Chemistry Expert System," which helps companies to identify and design more environmentally benign chemicals. The software includes five modules that allow users to build green chemical processes, design a green chemical, or survey the field of green chemistry. The "Synthetic Method Assessment for Reduction Technique" (SMART) module helps chemical companies to assess, in advance, the pollution prevention opportunities of new chemistries by quantifying and categorizing the hazardous substances used in or generated by a chemical reaction. Reactions can be modified in the SMART module and re-evaluated to optimize their potential health and environmental effects. Additional modules on green synthetic reactions, designing safer chemicals, and green solvents/reaction conditions provide information on alternatives and offer guidance on how substances can be modified to make them safer. A Green Chemistry Reference guide provides several search engines for acquiring additional information.¹⁸

Firms also have created tools for guiding their selection of chemicals in designing products and processes. For instance, S.C. Johnson has developed a tool called "Greenlist," which relies on two sets of criteria: one to establish the function use of chemicals and the other to measure the environmental and health impacts. Chemicals are placed into functional categories, such as surfactants, solvents, and adhesives, and then scored against a set of selected criteria such as aquatic toxicity, biodegradability, and vapor pressure, for comparative analyses within each category.

OPTIONS FOR PROMOTING ENVIRONMENTALLY SENSITIVE CHEMICAL INNOVATION

The United States has a long history of providing incentives for innovation in the chemical industry. Over the years, the government has employed different initiatives, such as tariffs, patent protection, tax incentives, preferred purchasing, and direct subsidies for research. These same government instruments could be used today to promote environmentally sensitive chemicals innovations.

There are six general policy tools that governments (national, state, or local) could use to promote the development and diffusion of innovation in green chemicals, biopolymers, and sustainable materials. They include:

- Research and development support;
- Technical assistance;
- Education and training;

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- Market interventions;
 - Economic policies; and
 - Regulations.

A. Research and Development Support

State and national government agencies have long supported research into new material and chemical streams. During the 1940s the federal government invested heavily in the Rubber Reserve Program to develop a synthetic rubber. Cut off during wartime from the natural rubber plantations of Malaysia, the government brought together the four leading rubber manufacturers, Standard Oil, and Dow chemical to develop synthetic rubber based on styrene and butadiene.¹⁹ Today, the federal government is laying out more than \$1 billion per year for research into nanotechnologies under the National Nanotechnology Initiative, which is arguably the largest chemical research program in the nation's history.

To encourage green chemistry research:

- **Government funding programs could be established to support green chemistry and sustainable materials research.** During the 1990s the National Science Foundation provided a small funding source through its "Benign by Design" initiative and the US EPA provided research support through its STAR program and another called "Alternative Synthesis Pathways for Pollution Prevention." The U.S. House of Representatives already has passed a bill, H.R. 1215, Green Chemistry Research and Development Act, which would provide annual appropriations for research on environmentally benign chemical products and processes. The bill is currently stalled in Congress and requires action by the Senate.
- **Green chemistry research could be promoted at state or national labs.** Sandia National Laboratory in New Mexico has a history of research programs on Environmentally Conscious Manufacturing and there is current work there on adhesives modeled on mastics produced by abalone. Other research is being conducted on renewable energy at the National Renewable Energy Lab in Colorado.
- **State or federal governments could establish Green Chemistry Initiatives** to coordinate agency efforts. California and Michigan have recently launched such an approach. A cross-agency research and development program could be developed similar to the National Nanotechnology Initiative that could appropriate money to different federal agencies to promote greener chemicals and bio-based materials.
- **Consortia of state research universities could be established to support green chemistry.** Higher education institutions could be encouraged to form strategic partnerships and alliances to educate, discover, develop, apply, and promote green chemistry and jobs creation on greener materials development. There is already collaboration among the public sector universities in New England called the New England Green Chemistry Consortium, which has received federal support through a three-year grant from the U.S. EPA.
- **Government agencies could budget more funding for green chemistry** and alternative chemicals promotion programs. For instance, funding for the federal Green Chemistry

and Design for the Environment (DFE) programs could be increased. The U.S. EPA's Green Chemistry Program was originally established as part of the Office of Pollution Prevention and Toxics Design for Environment Program. The DFE program assists industry sectors in developing alternatives to hazardous chemicals such as a current project on Alternative Assessment for Flame Retardants in Printed Circuit Boards. The Green Chemistry and Commerce Council (www.greenchemistryandcommerce.org), an informal industry group, has written a letter to the U.S. EPA administrator encouraging more support for the DFE and Green Chemistry programs.

B. 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. More than 30 states set up programs that offered workshops, conferences, on-site technical advice, information, research assistance, and various forms of awards and public recognition. In a smaller number of states, including Massachusetts and New Jersey, these technical assistance programs were established within the context of regulatory programs that required certain firms to participate and report on their effectiveness in reducing the use of certain toxic chemicals and the generation of hazardous wastes.

Governments could promote green chemistry innovation through technical assistance:

- **Those states with active pollution prevention programs could integrate green chemistry** and chemicals innovation assistance into their on-going technical assistance programs. Such programs could establish and maintain multi-stakeholder dialogues of vertically linked firms — so called “supply chain dialogues” to encourage information and problem sharing to facilitate innovation. The Office of Technical Assistance and the Toxics Use Reduction Institute in Massachusetts have been strong advocates for green chemistry and have worked with the University of Massachusetts in holding annual green chemistry conferences targeted at linking university faculty with industrial managers.
- **Governments could provide technical assistance materials** and tools to facilitate the development of green chemistry innovations. The U.S. EPA's green chemistry computer-based decision-making tools are one example. Guidance manuals and case studies also can provide encouragement and motivational incentives.
- **States could establish executive green chemistry commissions** that coordinate state assistance programs and provide a strong focal point for industry in promoting environmentally sensitive chemicals innovation. In 2004, the University of California at Berkeley presented a report recommending a green chemistry program for California and there are current initiatives in the state legislature to take early steps on that proposal. The governor of Michigan established a commission on green chemistry in 2005 and similar commissions have been proposed in New York, Maine, and Massachusetts.
- **Universities or non-governmental organizations can also be conveners of innovation-focused industry dialogues** to promote green technologies and bio-based materials by

prioritizing needs that require changes in process chemicals or the design of chemical products. The Green Chemistry and Commerce Council established by the Lowell Center for Sustainable Production or the Business/NGO Working Group for Safer Chemicals and Safer Materials organized by Clean Production Action provide useful models.

C. Education and Training

Education of young people can have a dramatic effect on the diffusion of new ideas, however, the timeline is long and unpredictable. Currently, there is a significant shortage of college students interested in chemistry and, therefore, few graduate chemists with much awareness of green chemistry and bio-based materials.

There are several ways to encourage environmentally friendly chemical innovations through education including:

- **Promote college courses in green chemistry and bio-based materials.** Some 16 colleges in the United States provide special courses in green chemistry. Even more effective would be conventional chemistry programs that offer toxicology and environmental science and policy courses as part of their curriculum.
- **Provide scholarships and graduate student support.** Student support often can provide inexpensive initiatives that encourage students to become eager promoters of new approaches. Such programs could be offered on a competitive basis to increase the impacts.
- **Encourage K-12 education programs.** The Center for Green Chemistry at University of Massachusetts Lowell requires that all doctoral students and all center research staff spend a portion of each month doing outreach to local high schools and primary schools teaching about green chemistry. Summer teacher training programs can add to such diffusion programs.

D. Market Interventions.

Governments purchase large amounts of commercial products. Indeed, in some markets, government purchasing is so significant that it drives market behavior. Federal, state, and municipal government resources could be directed to purchase green chemistry and bio-based products.

- **Government environmentally preferred procurement programs could be expanded and focused on green chemistry promotion.** There are several Presidential executive orders that already encourage environmental considerations in federal purchasing decisions. The new Bio-based Products Preferred Procurement Program (when its final rules are published in the Congressional Register within the next nine months) will require that all federal agencies purchase bio-based products when they are available, affordable, and perform as indicated.
- **State and municipal environmentally preferred procurement programs could be focused on products made from green chemistry processes.** Many cities, such as Seattle, Portland (Oregon), and Santa Monica, have well developed environmentally preferred purchasing

programs. The San Francisco City Council has adopted an ordinance for a precautionary approach to purchasing environmentally friendly products and Buffalo has made a commitment to purchasing products free of persistent bioaccumulative toxins.

- **State or national governments could establish certification programs to label products developed through green chemistry.** The labeling programs for organic foods, energy efficiency, and sustainable forestry sourcing have proven the effectiveness for consumers of labels that are easily accessible and understood.

E. Economic Policies

Governments can affect the innovative behavior of private entities by selectively using fiscal and economic tax and trade policies to financially reward companies.

- **State or federal governments 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. Governments have used tax deductions, accelerated depreciation schedules, or simple rebates to encourage preferred products (for example, energy conservation, solar collectors, hybrid vehicles.)
- **Federal policies could target agricultural subsidies** to farmers to produce crops for bio-based chemical production that are certified as produced following sustainable agriculture principles. For instance, the Institute of Agriculture and Trade Policy has suggested using sustainable agricultural certification criteria for guiding the funding for bio-based materials development authorized under the 2001 federal Farm Bill.
- **Federal or state programs could tax substances of high concern** to increase their costs, thereby encouraging green chemistry research and the adoption of less hazardous chemicals. In the phase-out of ozone depleting chemicals, the federal Clean Act Amendments of 1990 placed a tax on chlorofluorocarbons. States already tax cigarettes and gasoline to encourage use reductions.

F. Regulations

Government regulations can play an important role in driving innovation (see Rossi, Module 5). Federal, state, and local authorities have broad rule-making capacities that can affect the innovative, commercial, and investment behavior of firms. Laws that phase out the use of particular chemical substances or establish programs for substituting hazardous chemicals with more benign substances have an indirect effect in promoting innovation and green chemistry. For instance, the EU's Restriction on Hazardous Substances Directive specifies restrictions on the use of mercury, lead, cadmium, hexavalent chromium, and several brominated flame retardants in electronic products.

- **Government agencies could use existing or new legislation to ban specific chemicals** in ways that open markets for safer substitutes. For example, several states have passed laws phasing out the use of chemicals of high concern. Some states have enacted laws phasing out mercury in some products. States such as California, Maine, and Washington have passed laws phasing out the use of the flame retardant polybrominated diphenyl ethers (PBDEs).

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- **State or national government agencies could use various pre-regulatory techniques** to signal potential regulatory actions that encourage green chemistry research and shifts in chemical preferences. The Swedish and Danish governments have created so-called “Observation Lists” to draw public attention to chemicals that should be avoided where possible, even though there is no current plan to initiate regulatory procedures. In the United States, the federal Toxics Release Inventory list or the California “Prop 65” list have been used by firms to guide their decisions on chemicals to replace.
 - **State or national legislatures could enact chemicals policy legislation** that encourages a shift from hazardous to safer chemicals. In Massachusetts a bill entitled, An Act for a Healthy Massachusetts: Safer Alternatives to Toxic Chemicals, has been introduced into the legislature. It would create a priority list of substances and a comprehensive program to replace toxic chemicals with safer alternatives in consumer products and other businesses.
 - **Government legislatures or agencies could adopt policies that reform** the way chemicals are registered and evaluated for human health and safety and environment attributes. The University of California’s recent report, *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation* recommended state legislative initiatives modeled after the EU’s Registration, Evaluation, and Authorization of Chemicals (REACH) program that would close scientific research information gaps on chemical effects.

CONCLUSION: COMPARING OPTIONS FOR PROMOTING INNOVATION

The transition toward green chemistry and more sustainable chemical products and processes in the chemical industry will not be simple, quick, or easy. No one policy option will succeed without the support of other policy changes. Some options are likely to engender significant resistance not only from business interests, but, also, from those who might lose jobs or experience other dislocations. Other options can be implemented more easily, but the impacts will be more gradual and incremental (See Figure 3).

Stringent and time-limited regulations can be well-targeted and effective pull policies. Mandatory bans on the manufacture and use of specific chemicals can be timely and efficient, but the political costs are high and the promise of achieving safer substitutes is not assured. Past experience suggests that such bans often require extensive exemptions, push continued chemical production and use to other nations, and, if not well enforced, create illegal “black markets.” Less prohibitive regulation on the use of chemicals or the release of chemicals during their lifecycle can raise the costs enough to encourage the adoption of available substitutes and drive scientists to invent new substances or processes. However, there will be strong industrial resistance to more such regulation and the enforcement and compliance costs for government can be quite high.

FIGURE 3 Comparison of Policy Options

Option Type	Target of Intervention	Ease of Implementation	Cost of Implementation	Time to Achieve Impact
1. Research and development	chemical inventor, chemical manufacturer	easy	high	short
2. Technical assistance	chemical processor, chemical product manufacturer	easy	moderate	short
3. Education and training	chemical inventor	moderately difficult	moderate	long
4. Market intervention	chemical product manufacturer, retailer, user	moderately difficult	low	short
5. Economic	chemical manufacturer, chemical processor, chemical product manufacturer	difficult	high	medium
6. Regulatory	chemical manufacturer, chemical product manufacturer	moderately difficult	moderate	medium

Policies that change government and large consumer procurement practices are an example of an innovation pull policy that tries to link the market preferences of product purchasers to chemical manufacturers. Such policies are not particularly expensive and are usually reasonably accepted by most participating parties. Where the participating institutions have large market shares, the policies can be timely and efficient and, to the degree that they form consistent market signals, their impact may go well beyond the targeted products.

However, “pull policies” cannot succeed without innovation push policies. Policies that support research programs by redirecting current research support expenditures to universities or re-focusing the research conducted at the national labs to promote green chemistry alternatives can be implemented without statutory changes and through simple budget language changes. While such efforts will go against entrenched research priorities, they can be accomplished without new funds. Those policies that involve more government spending (such as H.R. 1215) will be attractive to both industry and non-governmental advocates, but they will strain the budgets of governments trying to hold down costs.

Education and training programs also can serve to push green chemistry. Such programs are usually inexpensive and non-controversial. However, they do not have immediate payoff and the results can be quite diffuse.

Fiscal and monetary policies are fairly crude push policies. While they are attractive to those who experience economic benefits, they are hard to target to specific outcomes. They can also become quite a large expense on government budgets and, because of their largess, they can be difficult to terminate, even once their objectives have been met.

Finally, there are the facilitative policies. Technical assistance and information generation and transfer policies offer little to promote invention, but can be important determinants of the rate and success of adoption of chemical substitutes. Indeed, technical assistance agents (government agricultural extension service agents or pollution prevention technical assistants) have been recognized as important factors in the process of diffusion of innovations. While the effects of these policies can be difficult to assess and they can be costly in terms of government expenditures, the experience with state pollution prevention programs demonstrates their popularity and usefulness.

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MODULE 6

Implementation of Chemical Policies within States: Competencies and Institutions

■ AMY D. KYLE

Implementing chemicals policy reforms at the state level must address issues of choosing institutional forms, assigning responsibilities, obtaining necessary authorities and funding, securing expertise, and “designing in” transparency and accountability

Public policy development requires deliberation over substantive proposals to achieve particular goals. It also involves consideration of means to implement those policies selected.

In the U.S., states have become the most important venue for development and adoption of new programs to assess and manage chemicals with regard to environmental protection and public health. Other modules in this report have described state programs to phase out use of mercury, to implement toxics use reduction, to reduce use of hazardous substances in consumer products such as electronics, and to warn consumers about hazards in products they buy. Each addresses a part of the larger chemical policy problem.

The question now is how states can move toward more comprehensive solutions. The modules in this report lay out options for many aspects of chemicals policy. This one focuses on what it takes to implement such policies.

This module considers capacity and related competencies, institutional forms, the importance of developing funding streams, accountability and transparency, and obtaining expertise. Such topics must be addressed if policy options are to be turned into effective action on the ground. Infrastructure must be created to allow policies to be implemented successfully to achieve intended results.

To move forward, advocates for state chemicals policy reforms must figure out how to get state initiatives started, particularly in the absence of a federal role to lay out initial parameters and provide funding.

In most areas of environmental protection, federal agencies play a catalyzing and funding role for most states. Many environmental protection authorities are delegated to states from the U.S. Environmental Protection Agency (U.S. EPA), and funding agreements support some percentage of state efforts. The interactions also enhance dialogue among states. In the absence of a federal role, strategies to allow states to develop capacity and funding streams are needed.

States undertake some programs that are not federally mandated. Management of solid waste and oil spill prevention and clean-up are examples. Solid waste management is a government function that people notice on a day-to-day basis and expect to be addressed. Oil spill control and clean-up programs first appeared in states where the issue became highly salient to the public. It suggests that success will require public engagement and support.

Chemicals policy initiatives will likely need “champions” within legislative and executive branches. Proponents of change should identify and join forces with strong leaders who are willing and able to develop, shape, and push legislation reflecting policy proposals and then to pay attention to administrative implementation. Such “champions” are especially important in new policy areas. They often look for on-going assistance and technical support, ranging from review of options to development of language for legislation, to creation of supporting testimony and participation in hearings.

It is also helpful to find allies within administrative agencies. Agency leaders can play significant roles in building support and creating institutional space for new initiatives. It is difficult to start up new programs that lack external mandates and funding without internal champions.

Funding is often a make-or-break question. Few environmental protection agencies have significant discretionary funds unless they can retain penalty or settlement dollars from legal actions. This means that few leaders can make commitments to new directions without funding sources because doing so would mean pulling away resources already committed to other areas. So the question of who pays for chemicals policy initiatives needs to be addressed as an overarching policy concern. Whose responsibility is it to pay to reduce the burden of chemical contamination in the U.S.?

Clearly, many opportunities are available, and states provide a great venue to try them out. The competencies needed and relative advantages of different institutional forms vary with the substantive chemicals policy options selected. Because the administrative implementation depends on policy options chosen, this module does not lay out a series of options. Rather, it identifies elements likely to be needed under multiple options.

CAPABILITIES AND COMPETENCIES FOR IMPLEMENTATION OF CHEMICAL POLICIES

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, several elements apply to many of the possibilities. This section identifies capabilities likely to be needed and reviews examples of existing models.

Agencies will need to be able to do these tasks, discussed in the following sections:

- Keep track of information;
- Develop regulations, directives, procedures, and protocols;
- Obtain and assess data;
- Disseminate and translate information and judgments for relevant audiences;
- Make decisions about warnings, substitution, controls, use restrictions, or phase-out of chemicals;
- Enforce required policy elements or decisions; and
- Provide technical assistance.

Agencies may begin by defining what matters for the implementation of their selected policy options. The substantive policy goals need to be considered in terms of what they mean for the topics shown above. Consideration can mean defining what chemicals are slated to be included in a use reduction program, for example. If states are to conduct their own reviews of chemicals, then it means defining the traits that will be reviewed. If a program will focus on meeting targets for reduction in use or release of hazardous chemicals, it could mean considering how they can be measured. An initial strategic review of what the key elements are and who should do what to achieve them will inform the development of the specifics.

A. Keeping Track of Information

As indicated in the preceding modules, data and information are important to chemicals policy. Under almost any policy option, it will be important to keep track of information, make data available for analyses, and accommodate sharing of information.

As is true with any evolving policy area, large volumes of new data and information will be generated over time. Moreover, information requirements also will change over time as knowledge and understanding increase. To accommodate expected change, both the design for information systems and the technology used must be flexible so they can provide enhanced capacity and new capability as requirements and knowledge change. This factor has become a fairly standard element of systems design.

The information system will require significant design and resources to integrate the information technology (IT) system with the “people network” of those who will want to use it. Plans to actively assist users to learn and grapple with the IT system will enhance this connection. The term

“knowledge management” is often applied to refer to information systems that integrate hardware, software, and human elements and are designed to address both individual and institutional needs for information and analysis.

The information that must be tracked will include the types of technical information discussed in previous modules. Technical data also will require storage, access, and retrieval. Presentation of data and findings for public audiences will need to be built into the system.

Equally important is information about programmatic requirements, which are likely to be complex. One simple example would be to identify which of the universe of chemicals in use are considered to be covered by a reporting system or other requirement. This appraisal could include a few listed as “chemicals of concern” or it could start from an inventory of all chemicals in use. Examples of data elements for chemicals that might be tracked for programmatic reasons are identifiers; manufacturers and users; data or testing requirements; any applicable screening requirements; results of assessments; any use restrictions or limitations; provisions for “take back” of products containing the substance; pending requirements for additional data, assessment, or action; and uses reported up and down the supply chain.

If limitations on access are prescribed as a result of concerns about confidential business information, trade secrets, enforcement action, or for other reasons, it would require levels of access that vary for different types of users (see Massey, Module 2).

Development of such data systems requires expertise in data management and access, networked applications, and data sharing among diverse parties. It also requires input to ensure that the needs of the users are accommodated.

Particularly for data about the chemicals (as opposed to management of the chemicals by a responsible agency), data management functions could be housed within management agencies or in other types of entities such as resource or research centers. However, data and information that pertain to enforcement matters, to trade secrets, or to confidential business information generally would need to remain in the custody of the management agency.

Existing data systems might provide models in certain respects:

The Chemical Abstracts Service¹ provides unique identifiers for chemical compounds. This is important because nomenclature used for chemical compounds is not standardized, and there are often several synonyms for a single substance. This system supports an enormous number of entries and provides a model for identification.

The systems used for Federal Insecticide Fungicide, Rodenticide Act (FIFRA) registration and tracking of pesticides provide models that may be informative, particularly for records related to use restriction, labeling,² and for records related to individual products.³ The number of

chemicals included is smaller than the number likely to be included in a system for industrial chemicals. Public access can be difficult because information is distributed into multiple sub systems and because some data has to be downloaded and transferred into database software.

An information system developed by the Organization for Economic Co-operation and Development (OECD) can be searched for records from several sources for individual chemicals.⁴ These sources are reported separately. This system provides more complete and accessible information but does not reconcile various sources into a consistent and understandable format.

Some of the data management systems of the National Library of Medicine, particularly ToxNet, might offer useful models because the design provides a unified window into various databases.⁵ However, data have to be searched individually by chemicals and some of the information is retrievable only by paying a fee.

B. Developing Requirements, Regulations, Protocols, and Procedures

Decisions and actions by government agencies differ from those of individuals or other kinds of institutions because the government has an obligation to conduct its business and impose requirements in predictable and transparent ways. Central tenets of administrative practice are that everybody is to be treated the same way and that everybody should be able to understand what the rules are. This framework imposes a significant burden on agencies to articulate in advance who is required to take specific actions, exactly what the actions are, and what the consequences of taking the actions or failing to take the actions would be. Governmental agencies generally cannot easily improvise or “make it up as they go along.” It also means that it is difficult for agencies to rapidly adjust and adapt as they learn more about the nature of the problem. They have significant information burdens to meet that are different from what other kinds of organizations face. Agencies often need to develop written policy statements, regulations, directives, or protocols. Meeting this obligation can be technically and politically demanding, partly because administrative actions and agencies are closely scrutinized by entities that they regulate. This section covers examples of areas for such requirements and protocols.

Information Needs

The modules in this report have emphasized needs for information about chemical traits and uses. The information needs for policy initiatives should be defined.

If a state is to review individual chemicals, then an initial need would be to identify the traits of concern. Examples might be topics such as “aquatic toxicity” or “potential to cause cancer.” Defining traits of interest remains an area of active policy debate. Much of the work being done in chemicals policy focuses on hazard traits that have been under discussion and review since the 1970s and few have incorporated more recent scientific findings about the importance of endocrine disruption, immune function, or neurological or neurodevelopmental effects, for example. States

will have to decide whether and how to address them. A second consideration is whether to focus on intrinsic properties of chemicals, which can be assessed one time and which do not change with use patterns. Such traits include physical and chemical properties, including persistence and tendency to bioaccumulate, as well as toxicity in all its forms. The Globally Harmonized System for hazard data organizes data about chemical traits that are intrinsic, for example.⁶ Some policy approaches also consider in chemical reviews information about exposure to chemicals. As noted elsewhere, exposure is not an attribute of the chemical itself, though certain chemical traits can increase the likelihood of exposure in particular circumstances. Studying exposures can be informative but imposes extensive additional information burdens on the agency. Knowledge of the current state of research and science is helpful for an agency to select traits of importance for a particular policy context.

Additional kinds of data in addition to data about traits of chemicals may be needed by some policy approaches. Information about production volume or chemical use is important to many policy alternatives and is needed, for example, to plan or evaluate use reduction projects and produce inventories of materials in use.

Policies that involve substitution or alternatives assessment, for example, require capacity to ensure that data are available to allow selection of alternatives that are truly safer. It would be important to make transparent what is known about the important chemicals traits.

The information needs for chemicals policy are extensive and may require ability to interpret data as well as to collect it.

Similarly, if chemicals policies require assessment of lifecycle impacts, then additional factors also must be considered. Strategies that focus on products would have to develop information requirements and assessment approaches relevant to products.

Data Quality

Ensuring the quality and validity of data and information submitted is important. Especially if data production requirements are imposed on manufacturers or users rather than independent research institutions or government entities, confirming data submittals would be an important responsibility.

There are two principal means to verify data submittals. One is to provide oversight of laboratory operations through some form of certification or accreditation program. Such programs are commonly employed for private laboratories that perform tests that are required by government agencies such as public health agencies. Such laboratories might run, for example, samples of drinking water required under federal and state monitoring requirements.⁷ Certification can include requirements for proficiency testing, lab audits, and use of established methods.

Certification for particular methods of analysis is also applied to state-run laboratories, such as those used in meat inspection programs.⁸ Certification for particular methods of analysis is also applied to state laboratories. Maintaining accreditation usually requires accurate performance on test samples provided by the certifying authority and audits of laboratories' procedures, including but not limited to quality assurance and quality control.

Such methods are better suited to ascertaining and documenting technical competence and performance than to detecting fraudulent results. They are also more common for analytic methods than for the types of bioassays often used for toxicity testing.

A second approach would be to use a different laboratory to reproduce results submitted to meet mandated data requirements. Such approaches do not appear to be as common as verification mechanisms in existing public health and environmental protection programs.

Some laboratory activities that have produced questionable data under other programs have been revealed by whistleblower reports from persons engaged in the work. It would be useful to consider providing whistleblower protection or perhaps rewards if interested parties are to be allowed to produce their own test data.

Quality and validity of data has been a challenging issue for all chemicals policy initiatives, in part due to the technical challenges associated with the methods used and in part because the policy outcomes are highly contested. The issue will require sophisticated attention from states.

Programmatic Requirements

Agencies adopt a wide array of procedures, regulations, and guidance to spell out specific programmatic requirements and what various parties have to do. Much or all of the requirements must be adopted through rule-making processes, which require notice and comment periods, as well as consideration and response to comments. Because of the complexity of many policy elements, considerable resources may be required for the procedural aspects of adopting such rules and procedures.

With regard to data and information, one key area would be to spell out who would develop or submit data required for the policy options adopted in each state. Rules would be necessary for each type of data and should define how acceptable data could be generated, addressing the issues of data quality.

C. Assessing Data and Characterizing Results

After an agency has decided what matters to its policy approach, a next step is to decide how to assess or interpret the information about the identified factors. The task could be done by identifying acceptable sources of existing information or by identifying acceptable means of producing new information.

As noted in the other sections of this report, data of many kinds may be relevant for chemical policy, including data about physical and chemical properties, acute effects on humans or animals or in assays, chronic or long-term effects, and so on.

The issue is probably of greatest concern in assessing information about traits of chemicals; key steps are to decide what kinds of data or test results will be accepted to determine the chemical traits. Denison (see Module 1, Denison) reviews options for data. None of the existing approaches is without controversy, unfortunately. And while it is possible and probably appropriate to rely on accepted testing methods for some traits, there are no generally accepted methods for some important traits of health concern. Among chronic effects, existing methods that are generally deemed to be acceptable exist for detection of mutagenicity, carcinogenicity, effects on certain target organs, and more obvious reproductive effects. Test methods for carcinogenicity have been controversial. Technical review of methods include adequacy of dosing with regard to timing and mode of delivery, power to detect effects, sufficiency of breadth of effects that would be found, relevance of route of exposure, adequacy of treatment of substances to avoid volatilization and other loss, and so on.

The key point is that an agency must have considerable expertise to make judgments about what kinds of data and information it will accept.

There is considerable interest in the development and validation of new methods such as shorter-term assays. As a practical matter, new methods may be needed because the data stream has been reduced in the U.S., partly a result of decisions by the National Toxicology Program to greatly reduce testing. The National Academy of Sciences recently released an analysis suggesting evolution in approaches toward testing.⁹

The critical issue is that, while deficiencies of existing methods have been identified, new methods are not available. Older methods are being questioned but replacement methods do not actually exist. There is no easy way for states to move into a new paradigm.

To agree on new methods would likely require considerable resources and significant time as well as mastery of the capabilities of existing methods, the relationships between short-term and long-term tests, and the limits of testing methods that exist to date.

It is also relevant to recognize that the issues to be addressed will not only be scientific. It can be anticipated that the materials interests of manufacturers to minimize testing requirements will be expressed during any developmental or review process.

For each major type of effect, multiple specific forms of data or test results could be submitted. In addition, for some compounds, studies in human populations, often in workplace settings, also may be available for consideration. For many policy options, some entity would assess the data available to reach summary conclusions that can be issued into forms that allow for policy action and comparison of different chemicals.

Synthesis and Characterization

Summary and synthesis of the data (experimental results and reports, published articles, other analyses) into a form that provides an official or credible interpretation of what they mean taken together might take the form of the development of an analogue of the “toxicity values” (for example, reference doses or cancer potency factors) that are reported into the Integrated Risk Information System (IRIS) database of the U.S. EPA or some other form. The point is to provide an expert consideration of all the relevant information and production of a standard way of characterizing what it means that can be compared across chemicals.

There are some existing models for assessing data, but all operate over a long time frame. All require some competency in interpretation of data produced through a variety of test methods. The greater the array of traits included in the data requirements, then the greater the breadth of expertise needed to integrate and interpret the data.

For example, the International Agency for Research on Cancer (IARC), an independent scientific organization sponsored by the World Health Organization and the French government, identifies chemicals or compounds that cause cancer.¹⁰ IARC may commission meta analyses (combined analyses based on several studies) and conducts full literature reviews. It convenes panels of experts on the chemicals or compounds that it assesses to review all of the available information about chemicals and then to classify the chemical with regard to whether it causes cancer. IARC does not provide any basis for comparison of the potency of individual chemicals or compounds. IARC has recently adopted guidance to prohibit participation in the deliberations of its expert panels by persons including scientists with conflicts of interest due to financial ties with entities that manufacture or profit from the use of the chemicals or compounds undergoing review.

In the U.S., the National Toxicology Program (NTP) has performed a similar role and issued a Report on Carcinogens in alternate years to identify chemicals that are “known” or “reasonably anticipated” to be carcinogens. The most recent edition includes 58 compounds “known” and 188 “reasonably anticipated” to cause cancer.¹¹ NTP convenes expert panels to review chemicals. It also has authority and facilities to conduct tests of chemicals. NTP conducts similar reviews for reproductive toxicants, though that effort is less extensive. NTP accepts nominations for chemicals to review. Like IARC, NTP does not produce quantitative estimates of the potency of toxic actions. NTP is housed in a government-funded research institution.

In its IRIS and associated reviews, U.S. EPA conducts a third assessment process for chemicals.¹² Unlike IARC and NTP, U.S. EPA does not restrict the types of outcomes it considers. The agency conducts most of the work internally, though draft documents are submitted for external peer review. Generally, EPA reviews evidence and studies related to cancer separately from those for non-cancer effects such as reproductive effects, neurodevelopmental effects, immune effects. EPA, like IARC and NTP, classifies chemicals with regard to the strength of evidence for whether they cause cancer. EPA also seeks to identify a “critical effect” among the non-cancer effects. This effect is one that occurs at the lowest dose (that is, after the least amount of exposure to the

chemical). If sufficient data are available, U.S. EPA develops a quantitative estimate to reflect the strength of the action of each chemical, doing this separately for cancer and for non-cancer effects. These values provide a way to compare the relative potency of different chemicals. Through its history, IRIS has assessed fewer than 600 chemicals.

All of these review processes are time consuming and cannot keep up with chemical use. States may want to adopt the results of the reviews by these groups but also need faster methods to assess data about chemicals.

These models for assessment are removed from requirements to submit or acquire data. Only the pesticides registration program under FIFRA in the U.S.¹³ and the California analogue program have the authority both to require the submission of data and to assess and then ultimately to act on the data. If state programs allow the same entities to review data and also require submittal of data, it may be possible to move toward more uniformity and completeness in the data available, which could make it faster and easier to come to a conclusion about the hazard traits of the chemicals.

Using Consistent and Comparable Protocols

One option that might reduce the considerable burden would be to better standardize testing requirements so that chemicals are tested using more consistent and comparable protocols. Doing so would reduce the need for interpretation and integration of data of different types and facilitate the comparison of different compounds. For specified data submittals, streamlined processes to convert experimental results, associated reports, or published articles into understandable entries could be established. This process needs to be designed so that it is largely self-executing, so data are swiftly made available.

A second option that might increase the pace of assessment of chemicals data would be to vest the responsibility in an independent agency that is not subject to lobbying by self-interested parties.

A third option would be to create health-protective defaults that would remain in place until assessments were completed. This approach is somewhat similar to the one used under Proposition 65 in California.

It is also important to note that all of these processes and models are geared toward assessment of chemicals expected to pose health hazards. The methods are not designed or geared toward identifying or assessing chemicals that might pose little or no hazard. They may not offer useful models to identify “safer” chemicals or to confirm that compounds represented as reflecting “green chemistry” are not toxic. If we shift our attention to finding materials with no or lower hazards, then perhaps the testing and assessments also could shift. It may be less important to document all hazards of the “bad” chemicals than it is to find the chemicals that have none of the hazard traits.

Current methods for assessing chemical traits are too slow and cumbersome. Data requirements must be better linked to assessments, so that the assessments are based on all of the relevant data and so that the patterns of data provided are more consistent and so more easily interpreted. More attention is needed to find the no and lower hazard materials, and it may require different methods.

D. Disseminating and Translating Data and Judgments for All Audiences

How to provide meaningful information to people about chemicals has received little attention. Characterization, translation, and dissemination are important because a variety of audiences and entities influence chemical use choices. They include both purchasers and users of chemical products and individual consumers. If a state policy includes actions by these entities, then particular attention to dissemination and explanation is needed.

Some form of coding or scoring is likely necessary to allow people to compare results for different chemicals. If state programs include elements for action by external parties, design of information to meet their needs is important.

For consumer audiences, the principal interest is in products rather than in ingredients. This means that the chemical hazard information must be provided for ingredients in products that people purchase. One approach might be to establish separate labeling requirements for consumer products, independent of what is required for chemical use reporting. There is a precedent for informing people about what is contained in their products, in FIFRA, which requires labeling, except of inert ingredients, in California's Proposition 65, which requires notification of exposure to carcinogens and reproductive toxicants if exposures are likely to create risks over safe harbor levels, and in the newly adopted Safe Cosmetics Act in California, which requires labeling of cosmetics containing carcinogens, mutagens, or reproductive toxicants. Some precedent also exists in the hazard communication standard of the Occupational Safety and Health Administration (OSHA), which requires materials safety data sheets (MSDS) for chemicals used in workplaces.

How the "missing" data are represented is also important and may influence whether "precautionary" decisions can be made. If missing data are treated as lack of evidence, it reinforces the status quo and does not create any incentive to provide the data. Dissemination strategies need to show missing data as negative. When there are legitimate reasons test results are not needed, of course, such findings also should be included.

Defining ways to explain what is learned in state policy initiatives is important to building support and a base for action.

E. Making Decisions

As noted in other modules in this series, government agencies may be called upon to make many different kinds of decisions as part of chemicals policy programs. Different kinds of decisions

require different kinds of expertise, information, analyses, vetting, dissemination, and implementation.

The overall process of specifying government requirements might be seen as focusing in three areas — defining scope, actions, and consequences.

The term *scope* is meant to refer to what or who is covered by government mandates or requirements. For chemicals policy, it could mean what kinds of entities are regulated (for example, manufacturers, secondary users, purchasers or importers of chemicals, or of products) and what kinds of actions are to be addressed. The scope of the Massachusetts Toxics Use Reduction Act program, for example, might be described as including entities that own or operate facilities that manufacture, use, or process chemicals found on certain specified lists in volumes greater than certain specified amounts. The scope includes specification of entities, actions, and targets.

The second aspect is to decide what actions are to be done under the scope of the initiative. The agency will have to decide who will be required to act or give mandates to act under certain conditions. Examples of kinds of actions that have been discussed include:

- Reporting uses of chemicals included under the scope;
- Providing data and information about chemical hazard traits;
- Developing chemical use management or use reduction plans;
- Conducting monitoring or biomonitoring;
- Adhering to use restrictions or phase-out;
- Providing warnings or labels; and
- Reporting information about hazard traits.

The third aspect is to address consequences. What happens if a regulated entity takes the required actions and what happens if it does not? The government agency usually has to provide some guidance, though considerable discretion remains to the agency in most cases in seeking either administrative, civil, or criminal penalties available. How will the agency assess whether the performance was adequate or whether penalties are appropriate?

While much attention goes to decisions about chemicals and how to assess or describe or prioritize them for various purposes, the information needs of government agencies to support all of the decisions relevant to chemical policy implementation are far broader.

For new institutions, actions by legislative bodies, in this case state legislatures, are usually necessary to give an agency or agencies legal authority to take actions and make decisions. Legislatures also must provide or authorize funding and positions to carry out these functions. For any such policy approach, a statute typically would provide guidance to an executive or administrative entity that would then be authorized to take action to implement the statutory authority.

The executive or administrative agencies hire staff into authorized positions, acquire space, obtain equipment and support services before they begin to perform the mandated functions.

It usually begins with what needs to be done and consideration of the best ways to do it. Steps involve both substance and process.

Such administrative or management programs require:

- Identification of information needs and then a data stream to provide information necessary to make decisions;
- An administrative process to allow for the systematic review of the needed information and for consultation with other parties as appropriate;
- Substantive criteria and procedures for making decisions;
- Mechanisms to advertise any opportunities for public, interagency, or other external review or participation;
- Means to describe and disseminate the decision, such as a permit, license, plan approval, language for a label;
- Verification of any limitations on actions or follow-up for further mandates activities such as development of a plan; and
- Process to track information, analysis, decisions, and follow-up.

F. Enforcement of Required Elements

All of the requirements for data generation, use of specified experimental and laboratory methods and protocols, reporting of results, adherence to specified use restrictions or bans, reporting of chemical use, labeling, and so on will require capacity for enforcement. There must be some verifiable way to ascertain what the requirements are and whether they have been met. Requirements generally are adopted in the form of regulations, though other options are sometimes possible. It means that entities responsible to carry out specific tasks must be identifiable. Some entity should be authorized to acquire information about whether the tasks have been carried out and whether data and information submitted is truthful (that is, not fraudulent). It usually requires authority for inspection, verification, and acquisition of records through subpoena or other means. There must be capacity to hold some entity accountable for failures to carry out the required tasks. There must be some means of identifying who is responsible and for instituting penalties in cases of failure. Penalties must be severe enough to deter non-compliance.

Penalties available to executive agencies generally include:

- a) Administrative penalties (that can be administered directly by the agency; these typically involve fines or revocation of authorizations to conduct business or to emit pollutants).
- b) Civil penalties that are ordered by a judge as a result of a claim filed by the administrative agency through the courts. Typically, they involve higher financial penalties or more wide-spread orders to cease and desist operations.
- c) Criminal penalties are enforced through the criminal justice system, typically as a result of an investigation conducted in cooperation with law enforcement agencies such as state troopers, a criminal division in a state department of law or justice, or the federal Department of Justice. Such penalties can include jail time or probation. These penalties can be most effective in gaining attention from corporate entities that are often not much affected by administrative or civil penalties.

Environmental protection agencies usually are more familiar with enforcement and compliance than public health agencies. In fact, environmental protection agencies, especially at the state level, and especially in states that do not have substantial scientific expertise within their agencies, view themselves as primarily compliance and enforcement entities. These agencies are likely to be better situated to enforce defined requirements for chemical policies than to be able to develop them in the first place.

The difficulty in enforcing chemicals policy requirements would be to put them into terms that make it fairly straightforward to determine whether they have been met or not. They need to be clear, verifiable, and actionable. However, little in this history of chemicals policy has taken this form, and most interactions between agencies and regulated entities have involved considerable discussion, negotiation, and interaction. Both the TSCA and FIFRA processes display these attributes. How to take this to requirements that can be broadly understood and enforced will require attention to specificity. States may be better able to accomplish it than the federal government.

G. 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.

Technical assistance could be extended to any of the targeted audiences for chemical policies. Technical assistance could aim to convince groups to help them better understand data about chemical hazards as well as the importance of data gaps and ways to identify and pursue safer products.

Technical assistance could be extended to purchasers of chemical products as well, to help them determine how to select environmentally benign products or processes. Technical assistance to chemical manufacturers and users could help them analyze their practices and identify ways to improve. The Massachusetts Toxics Use Reduction Institute provides technical assistance to businesses and also provides training to Toxics Use Reduction consultants who then work with regulated entities. Technical assistance can also be designed to help regulated entities comply with requirements. Such assistance is often best offered directly by an agency.

A final form of technical assistance would be to provide on-going support and assistance to civil society by helping varied organizations better understand and respond to the challenges of widespread use and release of toxic substances.

These various forms of technical assistance could be housed in government agencies, non-governmental organizations, or educational institutions. Those that are most clearly related to understanding agency requirements and data sources might be housed in agencies. Technical assistance geared toward user groups could be housed in any form of institution.

Because states often have close working relationships with businesses, they can be well positioned to develop credible technical assistance programs and gain voluntary cooperation.

INSTITUTIONAL FORMS

Institutions are important for creating continuity and capacity for progress in government initiatives. Institutions can create a sense of purpose and culture directed toward achieving defined ends. They can marshal resources and act in ways that enhance understanding and create policy space to achieve objectives. These functions go beyond administration of programs.

How new responsibilities are placed within the existing array of institutions, and whether new institutions are created, can affect what happens.

Political scientists use the term “venue shopping” to refer to choice of institution to engage in a policy issue. The term can refer both to type of institution (legislative, judicial, or executive) and to the level of institution (local, state, federal, or international). Because institutions differ in areas of interest and associated forms of analysis, different venues may produce different policy outcomes. This phenomenon has probably been most fully explored for pesticides policy in Canada. In this case, appeals to local city councils to take action to reduce “cosmetic” use of pesticides for lawn and gardens were widely successful. However, appeals to agencies responsible for managing pesticides were not.¹⁴ One reason was that the city councils viewed themselves as responsible for the health and well-being of people under their jurisdictions. Also, non-expert city council members were better able to make common sense decisions to reduce unnecessary use of pesticides in the face of possible hazards to health. By contrast, agencies responsible for managing pesticide chemicals viewed themselves as having a dual mission to both manage and promote use of pesticides. The sense of mission of an institution is relevant to how it will approach a particular issue.

Political scientists also provide insights with regard to salience and complexity of public issues. To the extent that issues are perceived as being salient, meaning that they affect many people in important ways, and not too complicated, they are more likely to be addressed by representative institutions such as legislatures.¹⁵ To the extent that issues are perceived as being too complicated for a general audience to understand, they tend to be addressed in expert settings within government agencies, with less input and participation from those who may be affected. The perceived level of complexity of policy options adopted may affect what kind of audiences and institutions remain engaged in their implementation. Highly complex schemas are not likely to receive sustained participation or scrutiny from the public interest community.

How to design the right kinds of institutions for chemicals policy at the state or federal level has received little attention. Other models may be instructive. For example, the Food and Drug Administration (FDA) is responsible for assessment, characterization, and management of pharmaceuticals. It is located within a health agency and is part of the public health infrastructure.

It is most closely allied with the medical community. The agency oversees a testing program conducted by the industry that, while flawed and subject to conflicts of interest, is still far more sophisticated, better defined, and more rigorous than anything that exists for industrial chemicals. One essential difference relates to the legal authorities in that the FDA is charged to ensure that pharmaceuticals are both safe and effective. The model is imperfect but illustrates that it is possible to be far more serious about creating an effective institutional form than what has occurred with industrial chemicals.

Within states, institutional forms for environmental protection and environmental public health vary enormously. Some states put environmental protection and environmental public health in a single agency, as is done in South Carolina. Some states separate them, but the institutions into which the two parts go vary. Some states put environmental public health into larger agencies that provide public assistance and health services. Some put it in public health agencies, as was done with the recent creation of a department of public health in the State of California. Environmental protection can be placed in a single purpose agency such as the Washington Department of Ecology, or it can be combined with resource management functions in departments of natural resources. So, when we consider institutional forms to both house and nurture chemicals policy initiatives, we begin with a great diversity of existing arrangements.

A. Multi-State Organizations

Multi-state organizations might play a useful role in chemicals policy implementation for states. Because of the range of needs and responsibilities required for chemicals policy, it is likely to be difficult or impossible for most states to mount a full program by themselves, for reasons of funding, expertise, and political support. So, a possible role for multi-state organizations may be worthwhile to consider.

Some existing models may be relevant. One might be the Pollution Prevention Roundtable, which is a membership organization that caters to states but also provides a forum for discussion among a variety of entities that include state and federal agencies, individuals from resource centers, industry representatives, and others.¹⁶ This Roundtable provides two key functions of a multi-state organization. It compiles and disseminates resources and experiences among its members. It allows for exchange of information and group learning and it provides an opportunity for alignment of perspectives among participants. The Roundtable does not perform other functions that would be needed to implement policy, such as to operate programs, adopt requirements, or render decisions that are binding in any way. It also does not appear to offer advice to states about how to do so.

Another instructive example of a multi-state organization would be the Northeast States for Coordinated Air Use Management (NESCAUM). This organization is an association of the air quality agencies of the northeast states.¹⁷ It is explicitly a multi-state organization and does not invite other members. It provides a venue through which states can coordinate decisions and actions on air quality issues. NESCAUM is more developed as an institution in that it takes actions to

achieve outcomes identified by state members. NESCAUM is more than a forum and venue for alignment in thinking because it takes positions and conducts analyses in support of the policy interests of its members. Specific regulatory actions, however, such as issuing permits or taking enforcement actions, would be done under the authorities of the member states. NESCAUM is funded in part through federal air pollution funds.

Multi-state organizations for chemicals policy could take multiple forms, with different degrees of responsibility (See Appendix for a detailed overview of one such model, An Interstate Chemicals Clearinghouse). A minimum level of interaction could provide for information sharing and group learning and alignment in thinking, along the lines of a forum or roundtable. A second level of interaction could involve joint inquiry or analyses targeted toward the policy interests of the member states. States could cooperate and work together to explore approaches and develop comparable information. A third level could involve a more formal arrangement for shared functions, such as perhaps data management and collection. One might imagine that states might cooperate to devise and implement data systems for chemical use data, for example. They could develop a common approach to nomenclature and reporting.

A fourth level would be to create an organization that could jointly develop management or policy approaches intended to be formally adopted by individual states through legislative or administrative actions with an intent for cooperative implementation. This approach would require a far higher degree of interaction, as states would seek to develop policy approaches that could be supported by all. It would obviously be difficult, since individual states vary in terms of interests of their political leaders and legislators, as well as resources available and existing capacity.

There is also a “chicken and egg” problem in that it would be difficult to obtain state participation until some advance work had been done, but it would be difficult to do much advance work without state participation. It would typically require some commitment of political leaders to obtain resources to allow state representatives to participate. Such a group would require time to develop effectiveness and cohesion and to perhaps get to a point to propose joint initiatives and then seek funding from states. It would seem to be a challenge to obtain state participation in the beginning. There is no analogue available for the federal funds that contribute toward supporting NESCAUM, for example. States may be sensitive to demands that appear to be “unfunded mandates” or impose claims on their time and resources without providing funding.

Perhaps one way to develop such an organization would be to begin with grant-based extramural funding. Funding would likely have to be sustained for quite a few years to allow discussion and initiatives to mature to the point where funding from individual states might be won. It would likely be necessary to provide financial support for participation by some states indefinitely. It is far beyond the scale of funding that has typically been available for states from foundations.

Governance requires particular attention in a multi-state organization because such an organization does not have the chain of command or hierarchy that establishes governance within most agencies. A multi-state or even a hybrid or networked model of organization would have

to decide who has the authority to pose issues, what process is to be used for vetting or review, and who then makes decisions. Processes that allow broader participation by allowing many individuals to pose questions or issues for decision or that allow wide participation in review and vetting can be time consuming. It is a particular concern if participants are not co-located, so cannot rely on informal communication channels to help share information and process alternatives.

Choices also need to be made about accountability for multi-state organizations. In typical government organizations, governance is addressed through a hierarchical chain-of-command model. Authority to make decisions is typically specifically delegated. Review and vetting occur through relevant units of the organization though they may also involve advice from other organizations. Disagreements can be resolved through the chain of command, which typically converges at the cabinet level or below.

For multi-state organizations, the same kind of hierarchical relationships between participants do not exist. Some form of governance body or board of directors must be consciously created to set policy parameters and objectives. Such a group can oversee work of a staff, as an executive director and employees, or of members of the group itself. However, it is difficult to compel any kind of contribution, and such a group can function to the extent that it can maintain a common view about what to do and how to do it. Hybrid or networked models also raise similar questions about governance and accountability.

Maintaining cooperative and collaborative efforts over time can be difficult. People who bring the original energy to ground groups may move onto other areas. It is not necessarily the case that those who followed will be as motivated to take the actions needed to maintain cohesion and to achieve results. Also, few talented people in government have significant resources of unallocated time. New projects are added on top of old ones. While extra time commitments can be sustained for a year or two, they cannot usually be sustained indefinitely. So, institutionalization and support are needed.

States may benefit from pooling resources and expertise in multi-state organizations directed at chemicals policy, but finding ways to get started would be challenging.

B. State Institutions

Individual states also face decisions about institutional forms for chemicals policy implementation.

Several kinds of institutional forms might be considered. They include creating a single-purpose chemicals agency, developing a program within an existing public agency, creating a hybrid organization that combines elements of public agencies with elements of research entities, networking different entities together, and participating in a multi-state organization.

Perhaps most straightforward would be to establish a public agency that is responsible for all aspects of chemical policy. The agency would house the data system, conduct assessments,

develop and promulgate rules, procedures and protocol, disseminate information; make management and regulatory decisions; and conduct enforcement actions.

There does not appear to be an example of such an agency in the U.S. The Swedish Chemicals Agency (KEMI) might be the closest example.¹⁸ The advantage of such an organization would be to provide the greatest degree of internal coordination and unity of purpose and to provide a focal point for the development of expertise and capacity. Putting all functions within a single organization means that any disputes or turf wars can be resolved within the organization. The disadvantage would be the cost of building new capacity and the lack of integration with other operational areas.

A second option would be to establish a chemicals program within an existing state agency, most likely a public health, environmental health, or environmental protection agency. This approach would develop a new focus area within an agency with a broader mission.

Its advantage would be that the new functional areas could build on existing resources and systems, rather than beginning anew. They might include data management, rule making, and enforcement capability. A second advantage would be to fit chemicals policy within a broader environmental protection or public health mission that had existing political and institutional support rather than to create an entity that might be politically isolated. An example of this kind of an agency would be the pesticide registration and use reporting system in California.¹⁹ The program is largely housed within the Department of Pesticide Regulation, which is part of Cal EPA, though the implementation is conducted through county agricultural commissioners, who are independent, and risk assessments are conducted by a different office inside Cal EPA.

A third option would be to create an independent institution that integrates elements of public agencies and research organizations. The Toxic Use Reduction Institute in Massachusetts is an example of an independent organization that has both elements. The advantage of such a hybrid form of organization is that it can have a unified focus and that it can bring the knowledge base of a research institution to the implementation of a program.

A fourth option would be to use different organizations to perform different functions and to link them through an operational network model. For example, the information and knowledge management systems and perhaps the information dissemination responsibilities could be vested in an independent organization like the National Library of Medicine. The assessment functions might be vested in a scientific or professional organization. The decision-making and enforcement functions would likely be vested in a public agency.

CROSS-CUTTING ISSUES

Critical issues to be addressed in designing any form of administrative implementation are funding, transparency, and accountability to the public, and expertise.

A. Funding

Obtaining sufficient funding to support implementation of chemicals policy is an important challenge. It is particularly true at the state level, where many environmental health and environmental protection programs depend on federal support. Funding for public health and environmental protection programs is difficult to obtain in states. There is little base of state funding in environmental health, and even large and wealthy states such as California are highly dependent on federal dollars and grant funding for basic environmental health programs addressing such critical priorities as asthma, for example.

Environmental protection agencies generally have greater general fund support but still rely on federal matching dollars. State programs are often funded to allow for delegation of federal responsibilities. State environmental protection agencies also have in many cases adopted fees to support review, permitting, and inspection programs.

It seems to be easier to pass legislative initiatives to create new state authorities in environmental health than it has been to gain state general fund support for them. This fact suggests that more focused attention on funding strategies is needed. Few non-governmental organizations that promote chemicals policy reform have extensive knowledge of budget processes or track records of success in getting significant state funding for new initiatives. In some cases, legislation for new initiatives is passed but lacks sufficient funding or provision for administrative implementation.

Because state budgets are usually developed using the current level of existing funding as the starting point or baseline, it is very difficult to inject new funding. All new funding is highlighted for intensive scrutiny in such a budgeting process, even if the base is highly inadequate. Proposals for any enhanced funding or new programs usually have to compete for a limited pool of resources.

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. Such revenues or fees could be obtained from entities that are regulated by the state or receive benefits or services from the state.

To support implementation of new legislative proposals through general funds, typically some form of fiscal analysis or “fiscal note” would accompany a legislative bill. The form that this takes and the exact way that it interacts with the state appropriations process vary. Generally, a fiscal analysis accompanies a substantive bill through the series of hearings before committees with policy jurisdiction (usually environmental quality, health, or natural resources committees.) Then, a bill with fiscal demands will typically be referred to a finance, budget, or appropriation committee, where the fiscal impact is assessed. Exactly how the findings of the finance committee mesh with the state’s budget process varies from state to state.

It is important to understand how funds can be appropriated and to follow this process as carefully as the legislative process.

States also differ with regard to when such a fiscal adjustment initiated by legislation is visible in state budget documents and with regard to whether such a specific line item can be vetoed by the governor as part of a budget bill.

The second approach to funding is to create a fee structure. In California, for example, the state runs a program for pesticide review and registration that also includes authority to require testing data, authority to impose use restrictions or to ban uses, and oversight of applications, as well as mandatory reporting. This program is supported by a “mill” tax imposed on the sale of pesticides in the state.²⁰ The model would seem to be a plausible way to support chemicals policy as well.

Congress passed an act in 2003 authorizing U.S. EPA to collect fees for some of its activities related to pesticide registration as well, though it was coupled with shortened time frames for review.²¹

In Massachusetts, the Toxics Use Reduction Act, passed in 1989, established requirements for large chemical users to plan to reduce their use of identified toxic substances. It also created the Toxics Use Reduction Institute and a program of training and technical support. They are funded through fees assessed on the use of toxic substances.

There are some complexities in constructing fees, depending on state laws. Some states preclude “dedicated” revenue streams. Dedicated fees are those that come from a particular revenue source and are then “dedicated” to providing funding for a particular project. In states that prohibit such fees, fees must be paid into the treasury and then specifically appropriated to the agency by the legislature. States also may have rules that limit the purposes for which fee dollars may be spent or distinctions between “fees” and “taxes.”

Focused attention on funding is essential to successful state policy.

B. Transparency and Accountability

Providing for public transparency and accountability is essential to maintain a public interest focus in government. The continuing impetus for progressive action is maintained through involvement of the public interest sector.²² Designing ways to ensure that this oversight and involvement is integral to the design and implementation of chemicals policy will be essential.

Several elements of government initiatives can contribute to or detract from transparency and accountability.

Transparency refers to making it possible to see and understand what decisions are being contemplated and why, decisions that have been made, program requirements, results of reviews,

or analysis and reason for conclusions reached. Transparency means that the government explains what it is thinking of doing and why, what options it is considering and reasons for them, what it expects to be the results of its actions and decisions. It also requires that the results reached or information obtained be visible and accessible to outside parties.

Accountability requires transparency but is not the same. Accountability concerns whether the needs of stakeholders are considered in government actions and whether promises and commitments made are honored in meaningful ways. Accountability is also about whether goals or objectives identified for initiatives are met. It requires an articulation of what is to be accomplished followed by an honest and meaningful assessment of actual results to identify both successes and failures. When failures are experienced, accountability means best efforts to understand why and to plan or adjust to new approaches to achieve the purposes of the initiatives. Accountability can be increased when all of the inputs to any assessment are transparent so that analyses can be verified independently.

Mechanisms to promote transparency include active outreach to maintain awareness and connectedness between the government agency and its stakeholder communities, both of which will change and evolve over time. Combinations of old and new media methods are usually best to meet communication needs of diverse audiences. Active communication and updates allow stakeholders to identify issues of concern. Active review and vetting of proposed actions allow an agency to address concerns raised.

Transparency takes time and effort. It may be perceived as creating conflict because stakeholders have different material and public policy interests and will not always or often agree about best approaches. Transparency can bring these differences into focus but does not actually create them. It does allow an opportunity to address them within a program or initiative. Transparency can to some degree level the playing field between entities with greater resources and those with lesser resources because transparent processes require less time and energy to understand and track. So, transparent processes are more accessible to those outside the inner circle or not able to pay attention to the day-to-day workings of government. However, transparency does not eliminate the need for time, expertise, and commitment in any audience or stakeholder group to understand what is going on and advocate for policy interests.

Transparency and accountability are needed for government agencies to act in the public interest but they must be designed into the program.

C. Expertise

The question of how to build sufficient expertise in states to carry out the complex requirements to implement chemicals policy is a difficult one.

The scope of activity required for the development of guidance for the various kinds of information that might be sought is wide and combines a need for both diverse and deep technical

competence in a variety of disciplines, capacity to imagine how they can be applied in a management context; ability to manage a political process of negotiation that could lead to broadly supported approaches; and capacity to develop detailed guidance for experimental design. It is a tall order, as few entities or individuals span both technical competencies and the leadership and political management capacities that are required, and few agencies develop the combined technical and political leadership.²³

Few states have significant depth of expertise in toxicology or epidemiology. Most rely on technical guidance from federal agencies, sometimes supplemented by the work of one or two experts on staff. How to design state programs that have such capacity will be important to address.

In general, salaries for technical experts in states, even in large states such as California, lag far behind the market.²⁴ Partly due to lack of professional support, public service is less often seen as an appealing career choice among younger scientists. Most of the existing cadre of agency experts will retire in the next ten years and it is not clear who will replace them.

States may want to build partnerships with research organizations such as universities. In particular, state universities often have an element of service in their missions. However, most major research is funded externally, so, as with agencies, most investigators at universities are already highly committed to funded projects. Moreover, the principal goal of university researchers is to publish new research. A sustainable partnership would require funding over time.

A second option, not mutually exclusive, would be to find ways to provide competitive salaries and professional support for state agency experts.

Increased appreciation of the value of public service and more competitive salaries are likely needed to retain and attract scientists who can meet the significant technical and political challenges of chemicals policy implementation.

CONCLUSION

States offer essential laboratories to develop and test approaches to policy in many areas. Particularly for chemicals policy, states provide the venue in which actions are already underway and where policy development is most likely. Many policy options and alternatives are available. What all of them share is the need for authority and resources to allow administrative implementation. Without attention to implementation, even the best policies will not matter.

APPENDIX

Developing an Interstate Chemicals Clearinghouse

This appendix provides a rationale and outline for the establishment of an Interstate Clearinghouse on Chemicals (IC2) to provide a mechanism for collaboration and information sharing among states undertaking industrial chemicals management policy initiatives. In addition to providing value added support to state agencies, the Clearinghouse would also provide support to industrial firms and advocacy organizations.

BACKGROUND AND RATIONALE

Recent legislative initiatives in several states suggest a new wave of state activity on managing chemicals and chemical hazards. These initiatives range from coordinated efforts to phase out the use of mercury and prohibitions on the use of some brominated fire retardants to more comprehensive efforts to classify chemicals by hazard and encourage the substitution of those of highest concern with substances of lower concern. While the new chemical initiatives developing at the state level are varied in terms of goals and authorities, there are some common needs and functions that could be addressed by establishing an interstate institution.

The industrial chemical market in the United States is a broad and complex market. It will be a significant challenge for states to take on the substantial administrative and scientific efforts necessary to identify chemicals of high concern to human health and the environment, their presence in products, and to undertake assessments of safer alternatives. An interstate institution holds the potential for being an effective and efficient means for mitigating the high costs of individual states moving forward independently and trying to fill complex data needs, and coordinating functions that are common across states.

The U.S. Environmental Protection Agency provides both technical and financial resources to the states on air and water pollution and waste management through the delegated authorities of the various relevant statutes. However, the federal laws dealing with chemical management (the Toxic Substances Control Act) or hazardous chemicals in products (the Consumer Product Safety Act) do not provide for a delegated authority for the states. Therefore there is little federal technical and no financial support offered to state agencies dealing with chemicals management. While the EPA does manage various databases such as the Toxics Release Inventory, the Inventory Update and the High Production Volume Information System, the agency is constrained in its use of these information sources by significant pressure from the private industry sector. For instance the EPA has been restrained in creating any kind of national product registry, in collecting chemical use data or in tracking chemical flows through the economy. Years of experience has demonstrated

how politically constrained the EPA is in advancing or employing chemical management information systems.

Recognizing the limitations of the federal agencies and the growing needs of the states, there is a need for an independent, state-focused institution. An option to fulfill this need is the establishment of a new, multi-state institution, here referred to as an Interstate Chemicals Clearinghouse (IC2). The functions of this Clearinghouse would be:

- Maintain a database of chemical profiles that includes hazard and exposure data on individual chemicals;
- Maintain a registry of uses/use categories of high hazard chemicals (based on prioritization exercises done through the IC2 or other mechanism);
- Maintain a registry of products and/or product groups that contain high hazardous chemicals;
- Provide a clearinghouse for alternatives assessments (alternatives research) and a database of safer substitutes for chemicals of concern (by use type);
- Provide a forum for sharing information on safer chemicals initiatives at the state and local level as well as initiating interstate chemicals initiatives between states or with various stakeholder groups (such as supply chain dialogs, demonstration projects, etc.);
- Provide fact sheets and guidance documents on chemical use, hazards and substitutes;
- Provide a forum for receiving and disseminating U.S. Environmental Protection Agency chemical use and hazard data;
- Provide a forum for developing model programs among government agencies and other stakeholders; and/or
- Provide a forum for sharing of compliance and enforcement information.

In essence, the IC2 would bring together research and data gathered on chemical hazards, alternatives, and initiatives for implementation of safer chemicals policies by the states into a single location, while establishing new data, research, dialogs and collaborations.

There is a long history of states formalizing multi-state compacts and establishing multi-state institutions. The New York State Port Authority and similar water body compacts around the Chesapeake Bay, the Great Lakes and the Mississippi River provide ready examples. In the Northeast institutions like the New England Governor's Conference, the New England Council, the Northeast Waste Management Officials Association (NEMOA), and the Northeast States for Coordinated Air Use Management (NESCAUM) suggest the tradition of cooperative, multi-state institutions where states are geographically small.

LESSONS FROM CURRENT EXPERIENCE

Experience and examination of various regional, national, and state initiatives has indicated that several elements are of great importance in making such an interstate organization successful, including:

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- **A clear public purpose mandate with room for adaptation.** For a multi-state initiative, states may need legislative authorization to permit functional participation and resource contribution. Such a mandate would clearly outline the roles, responsibilities, and structure of government participation.
 - **An independent and well-respected governing board and professional staff.** A small governing board made up of advocates, government, and forward looking business representatives would be ideal.
 - **A secure and consistent funding base.** A secure and long term funding base is a critical need, given the lack of general support from private/government sources for such an institute. For a multi-state initiative, an industry fee may not be feasible in which case a fee paid by each individual state (as members of the Clearinghouse) would need to be assessed. It is likely easier that such a fee be built into the government executive order or legislation authorizing participation in such an organization.
 - **A dedicated staff of technical professionals.** A Clearinghouse needs a dedicated staff that are program based rather than project based ensuring that the overall mission of the organization can be carried out effectively. The staff would have a broad mix of technical and policy professionals — including engineers, toxicologists, and policy analysts.
 - **A strong leader.** A major determinant of success is a strong leadership that is able to advocate for resources and protect it from potential political implications of its work. Certainly, the director of such an institute has to have close connections to governments, businesses and advocate organizations.

ORGANIZATIONAL MODELS

In considering the establishment of this new Clearinghouse there are a range of models including the Massachusetts Toxics Use Reduction Institute (TURI), the Interstate Mercury Education and Reduction Clearinghouse (IMERC) set up at Northeast Waste Management Officials Organization (NEWMOA), and the Toxics in Packaging Clearinghouse (TPCH) administered through the Northeast Recycling Council. These different models demonstrate various strengths and limits. An institution set up at a university, such as TURI, provides for neutrality and legitimacy, but appears academic and limited in influence to a single state. The IMERC and TPCH demonstrate the advantages of an interstate organization sponsor; however both of these appear to favor the northeast.

This quick review suggested that the most appropriate model for the foundation of this new Clearinghouse would be an independent, non-profit corporation chartered solely to fulfill the state and local government needs. While such an organization would need time and experience to establish national legitimacy, its independence and singular purpose offer superior advantages.

The Clearinghouse would be open to any local or state government agency that is willing to contribute to the support of the organization. While this Clearinghouse would largely serve state needs and, therefore, states would be the participating members, there may be some municipalities or quasi-government authorities that could also join as participating members.

The Clearinghouse would need to assess each government agency an annual fee for participation and services. The annual base fee might be graduated on a formula based on size of the state or the size of the state economy and states that seek extensive services from the Clearinghouse might be assessed additional user fees based on the costs to the Clearinghouse of providing those services.

ENDNOTES

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MODULE 7

Applying the Chemical Policy Options to Emerging Technologies and Materials: Adaptations and Challenges

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Can the template developed in this report for chemicals policy reform be applied in assessing the hazards of emerging technologies and what considerations are involved for state governments?

As new discoveries are made, new truths discovered, and manners and opinions change with the change of circumstances, institutions must advance also to keep pace with the times.

— *Thomas Jefferson*

In the past, it has often taken a long time to identify and establish the direct and indirect short- and long-term risk and benefits of past “emerging technologies,” such as chemicals, nuclear power, and genetically modified organisms. The reasons are many. Some of them are specific to the nature of the emerging technologies in question; others, it seems, are constant from one technology to another. Society periodically faces the same kinds of situations with great proclaimed potential benefits for an emerging technology, but uncertainty or ignorance about its potential short- and long-term adverse effects on human health and the environment. Recurring problems include how to validate proclaimed benefits; how to establish hazards; problems estimating exposure; controversy about whether there is a safe dose of exposure and what it might be; whether the pros outweigh the cons; when we will know enough to implement regulatory measures; and whether lack of information justifies action in and by itself.

Although many of the questions are not new and have been discussed and written about extensively¹⁻³, they have yet to be resolved to the extent that they have been implemented proactively. Furthermore, they are not outdated since they keep coming up in the discussion of the “emerging technologies” of our decade, such as nanotechnology, stem cell research, biotechnology, and information and communications technologies. Explanation for why they recur could be that they are always relevant in an ever-changing society with changing priorities and values, and that the specific circumstances of the technology change markedly with every new technology so that it does not make sense to duplicate past practices employed on past emerging technologies.

However, under the assumption that it is not necessarily always the case and under the assumption that there is a lot we can learn from the past, the purpose of this module is to go through the previous modules and identify adaptations (if any) that would have to be made in order for the individual policy options to be applicable to today's emerging technologies, as well as to the chemicals for which they were originally intended. This approach will use different past and present emerging technologies and materials as examples of how the policy options identified in the modules can be implemented.

First, we provide a definition of emerging technologies and some examples of emerging technologies that are projected to have profound impact on our future. Then we discuss how to proactively identify emerging technologies. Drawing on Denison's work (see Module 1, Denison), we follow by analyzing how one can generate information to manage the technologies given their variety and the diversity of their future applications. Once they have been identified and initial information on them has been generated, Tickner's module (see Module 3, Tickner) is used as inspiration for what to do with this information and how to evaluate and prioritize various emerging technologies. A key element in the evaluation process of chemicals is the availability of safer alternatives, which — based on Rossi's module (see Module 4, Rossi) — will be discussed in the context of emerging technologies. Looking beyond the evaluation process, the timely flow of accurate information to the actors who make decisions is equally important, and a number of recommendations will be made drawing on Massey's work (see Module 2, Massey). This process leads to a discussion about which kinds of capabilities would have to be in place, based on the contribution by Kyle (see Module 6, Kyle), to oversee such multifaceted processes as the ones outlined by Denison, Rossi, Tickner, and Massey.

It is important to ensure that one is on the forefront of the development, information generation, and management of emerging technologies. Also important is establishing short- and long-term incentives to guide research institutions, industry, and others onto a specific innovative path towards sustainability by pre-defining a set of rules that any technology should fulfill. Drawing on Geiser and McPherson's module (see Module 5, Geiser and McPherson) on green chemistry, we discuss how such principles can be broadened beyond well-established technologies and become part of a proactive strategy for the safe management of emerging technologies. A comparison will be made between the policy options described in the modules applied to emerging technologies with a view to these criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution), and transparency. Finally, some reflections on what local and state governments can do will be provided.

DEFINING AND IDENTIFYING EMERGING TECHNOLOGIES

The term “emerging technologies” can be broadly defined as “science-based innovations that have the potential to create a new industry or transform an existing one.”⁴ According to a recent NIOSH publication on emerging technologies and the safety and health of working people,

“Emerging technologies exist where the knowledge base is expanding, the application to existing markets is undergoing innovation, or new markets are being tapped or created.”⁵ The term “emerging technology” is broad and a number of technologies have earned the label: from communications technology to biotechnology and nanotechnology (and various others in transportation, energy, and food handling). Here, **the term emerging technologies and materials is limited to those that affect manufacturing processes**, for instance, new materials, and it does not include emerging technologies that affect social interactions, such as the internet, cognitive radio, second life, and so on.

A vital first element of a proactive strategy on emerging technologies is to have a system in place that generates information that allows one to identify emerging technologies and materials. It could take the form of an agency, an office under an agency, or an intra-agency working group (see Module 6, Kyle) that have time and resources to look consistently for emerging technologies and materials. Given their nature, such an agency would have to be interdisciplinary and *not* media-specific. In some countries, such agencies exist already or are being set up. For instance, in the United Kingdom (UK), the Department for Environment, Food and Rural Affairs launched a Horizon Scanning and Futures Programme in 2002 and the government has committed itself to the establishment of a Centre of Excellence in Horizon Scanning, which aims in part to spot the implications of emerging science and technologies.^{6,7} In the U.S., the situation is rather strange since such an agency actually existed from 1974 until 1995 in the form of the U.S. Congress’ Office of Technology Assessment (OTA). When Congress voted to withdraw funding in what some have called “Death by Congressional Ignorance,”⁸ the OTA had more than 140 full-time employees who provided nonpartisan highly qualified and widely respected analytical assistance to Congress on complex highly technical issues.^{9,10} The reasons for setting up the OTA were much like the challenges today with emerging technologies. In the establishing OTA Act, Congress argued that:

1. As technology continues to change and expand rapidly, its applications are:
 - a. Large and growing in scale; and
 - b. Increasingly extensive, pervasive, and critical in their impact, beneficial and adverse, on the natural and social environment.
2. Therefore, it is essential that, to the fullest extent possible, the consequences of technological applications be anticipated, understood, and considered in determination of public policy on existing and emerging national problems.¹¹

Emerging technologies are fairly easy to identify since they signal their arrival long before they bloom into full-fledged commercial successes and their emergence is routinely covered by major scientific and engineering societies and journals.^{5,12} Further, several websites are dedicated to emerging technologies and studying the future (see NIOSH⁵ for a full list of web sites and other sources of information on emerging technologies). *Technology Review* from Massachusetts Institute of Technology has an annual issue identifying ten technologies the editors call the most “exciting and most likely to alter industries, fields of research, and even the way we live.”¹³ For the most recent technologies listed by *Technology Review*, see Box on page 208.

Most Recent Emerging Technologies

1. **Neuron control** which controls neural cells with flashes of light turning selected parts of the brain on and off providing precisely targeted treatments for psychiatric and neurological disorders with greater effectiveness and fewer side effects;¹⁴
2. **Augmented reality** which adds a GPS sensor, a compass, and accelerometers to smart phones making it possible for users to calculate distance, retrieves the names and geographical coordinates of nearby landmarks and restaurants from an external database;¹⁵
3. **Peer-to-peer (P2P) file distribution technology** which puts less of a burden on internet networks, saving bandwidth. In P2P networks, there are no central servers in contrast to current networks and each user's PC exchanges data with many others in an ever-shifting mesh;¹⁶
4. **Digital imaging and compressive sensing** which uses a single image sensor to collect just enough information to let a novel algorithm reconstruct a high-resolution image, saving energy since it does not need to compress images like today's digital cameras;¹⁷
5. **Light-focusing optical antennas** which increase the capacity of DVDs and the power of computer chips and higher-resolution optical microscopes by adding nanoscale "optical antennas" to a commercially available laser;¹⁸
6. **Quantum-dot solar power** which uses tiny crystals of semiconductors just a few nanometers wide to convert light energy into electrical current potentially making solar cells much cheaper and making solar power cost-competitive compared with electricity from fossil fuels;¹⁹
7. **Nano-healing** which uses the ability of nanoscale protein fragments, or peptides, to accelerate healing of damaged brain and spinal tissue potentially saving lives by stopping bleeding and aiding recovery from brain injury;²⁰
8. **Artificially structured metamaterials** made up of precisely arranged patterns of two or more distinct materials that can manipulate electromagnetic radiation, including light, in ways not readily observed in nature and which could transform telecommunications, data storage, and even solar energy;²¹
9. **Personal medical monitoring** which uses computer networks to help physicians interpret large amounts of physiological information, such as temperature and blood pressure readings, MRI scans, electrocardiogram (EKG) readouts, x-rays, and so on, making diagnostics more personal;²² and
10. **Single-cell analysis** which uses ultra-sensitive techniques to isolate cells and reveal molecules inside them that no one even knew were there and detecting minute differences between individual cells that could improve medical tests and let doctors quickly decide on proper treatment.²³

Not all emerging technologies, of course, will alter industries or the way we live or have potential impact on health and the environment. Being proactive in identifying emerging technologies and generating the initial information for management decisions might turn out to be premature, since the technology might never realize its potential. However, if this happens, the initial time

and resources wasted would tend to be small. They also would be outweighed by the occasions when the technology “makes it,” since the earlier agencies engage in the develop a new technology, the easier it is for them to secure an overview, follow its development, and determine whether it will indeed take off.

GENERATING INFORMATION FOR CHARACTERIZATION AND MANAGEMENT OF POTENTIAL RISKS

Once the technologies have been identified, four parts of Denison’s module (Module 1) on generating information become especially relevant: the types of decisions for which information is needed; types of information; testing and alternative methods to generate information; and government’s options for generating information.

Types of Decisions for Which Information Is Needed

The types of decisions for which information is needed have been controversial in relation to emerging technologies. The types of decisions seem to range from a ban of the technology to a laissez-faire attitude.

Multiple policy options are available for decision-makers engaged in managing emerging technologies, including:

1. Implementing a ban or a time-limited moratorium on research and development (R&D) and commercialization of the technology and products based on it, such as happened in the case of supersonic transport in the 1970s in the U.S.;¹
2. Implementing a ban or a time-limited moratorium on commercialization of the emerging technology only and products based on it, but maintaining R&D, such as happened in the case of research in recombinant DNA in Cambridge, Massachusetts in the 1970s and the commercialization of genetically modified organisms in the European Union (EU) in the 1990s;
3. Launching a comprehensive, in-depth regulatory process specific to the emerging technology in question with the purpose of forming and implementing a new regulatory framework that takes potentially widely different applications into consideration;
4. Adapting existing regulation so that it covers the emerging technology and ensures the generation of environmental, health, and safety (EHS) information and the protection of human health and/or the environment;
5. Initiating and funding EHS studies at government and non-governmental research facilities and collecting data about, for instance, production, use patterns, and best practices in relation to EHS;
6. Relying on voluntary environmental programs to ensure that human health and the environment are protected and EHS information is generated, such as the U.S. EPA has recently chosen to do in regard to nanomaterials;
7. Relying on current regulatory frameworks to cover the emerging technology and assuming that it is adequate to protect human health and the environment and generation of EHS information; and

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8. Relying on market forces to ensure that human health and the environment are adequately protected, such as in the case of many information and communications technologies.

Which one (or which combinations) of these policy options is eventually adopted by decision-makers will vary depending on the nature and the circumstances of the emerging technology as the modules in this volume illustrate in the case of chemicals.

Given the increasing pace of technological development and the increasingly complex and pervasive uncertainty about their potential beneficial and adverse impacts on the natural and social environments, identifying the right options or the right combination of options must be an iterative process between decision-makers, stakeholders, and the public.

Having the federal government develop an oversight system by itself is not an option in the case of emerging technologies simply because of the pace of technological development. The development of nanotechnology is a good example. The period before 2005 has been labeled the first generation of nanotechnology; it involved the exploration of passive nanostructures and materials, such as zinc oxide in sunscreen. Since 2005, the second generation has moved more toward the development of bio- and physico-chemical active nanostructures. By 2010–2015, it has been projected, scientists will employ guided assembly of nanosystems, and by 2015–2020, the field is expected to expand to molecular nanosystems or atomic design.²⁴

Given the high pace of development in fields such as nanotechnology, “it is both unnecessary and impractical to leave the oversight role entirely to a limited set of already overburdened federal agencies,”²⁵ Greenwood has stated. Developing adequate oversight requires federal outreach to stakeholders — such as industry, academia, non-governmental organizations (NGOs), and others — since these actors are the ones who know the technology “inside out” and they are involved in developing consensus standards, codes, and understandings.^{25,26} In the analysis of possible alternative developmental paths, clarification of all stakeholder interests is essential.^{26,27} One benefit of such outreach is that it limits the time of uncertainty about future government policies, uncertainties that can be problematic and anxiety-producing for innovators, potential investors, stakeholders, and the public.^{28,29}

Any discussions about what policy option(s) are preferable for emerging technologies has to include the public. It is important that discussions not aim to convince and educate the public about emerging technologies to have them accept the technology. That approach has failed stunningly in the past, for instance, on issues of food irradiation and genetically modified crops, for several reasons. First, it assumes that the experts know the true risk and, as Shrader-Frechette³⁰ has argued, often they do not. Second, it assumes that the perception of risk by laymen is wrong. Although they may lack certain basic information, their conceptualization of risk is richer than that of the expert, including factors such as considerations about uncertainty, controllability, the benefits of taking a specific risk, and threats to future generations.³⁰⁻³³ Third, when proponents of emerging technologies call for “public education,” they often mean public persuasion. It is

problematic because it not only assumes that the communicator knows what is true, but also that he or she knows what is good and right.³⁴

Although one should take care in drawing parallels through history, the cases of food irradiation and genetically modified crops underline that the public should be viewed as a legitimate partner and be involved in both the risk assessment and the risk management process of emerging technologies.^{25–28,35} Past experiences have shown that the public may contribute substantially to a scientific decision-making process.³⁶

The public may be involved in several ways: for instance, consensus or “layperson” conferences, scenario workshops, and science shops,^{37–39} but in many cases (for example, food irradiation), a “due consideration” model has been chosen in the U.S. Normally, it involves the agency (for instance, the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA)) taking a position in advance of public hearings and inviting public comments on its position. Afterward, the agency is obliged to give due consideration to all relevant facts and arguments and explain why it chose the option that it finally adopted.³⁹ These methods have a number of limitations. For instance, the regulatory decisions already may have been made, so that it cannot be said that the public was involved, but rather that it was allowed only to comment on the issue. Such a scenario would not really reflect the call for a more transparent and democratic decision-making process.^{26,27,37,38,40}

Under the right circumstances, public perceptions and reactions can override the customary workings of the regulatory process.⁴¹ Lessons learned from the debate about genetically modified crops (or genetically modified organisms (GMOs) in the UK stress the importance of considering the concerns of the wider public early during research and development when there is still time for the public’s views to inform the development of new technologies. Early public research on nanotechnology in the UK indicates that the public does not oppose it but has concerns about the path of innovation and the lack of regulatory oversight, offering an opportunity for governments to involve the public and address the issues.^{26,28}

Types of Information

A key question about generating information on emerging technologies is what types of information is needed to inform sound management. Due to the fact that emerging technologies and materials in industrial settings almost by definition would involve application and exploitation of properties not realized before, the new properties are where the focus should be placed in generating health and safety information. Information is needed about the new properties and characteristics: how to determine them; how they affect current methods used to establish hazards, exposure and risks; and — probably most importantly — whether current health and safety protection measures are adequate in the new context and circumstances. Ideally, the information would be available—and applicable — at all stages of the technology’s development, from basic R&D to full-scale commercial launch.⁴² For instance, in the case of nanomaterials, the exploitation of additional properties — size, surface chemistry, surface charge, and so on — is what makes

these materials so different from bulk chemicals. The hazards of nanomaterials would be related to their chemical composition, but also to the effect of these additional properties on biological activity and behavior that scientists do not fully understand now. So in choosing types of information to inform sound decisions about safe management, decision-makers need to include many (if not all) of the elements listed by Denison in addition to extra information that might tell where, for instance, the nanostructure is located in the system (that is, in the bulk, as surfaces, or as particles); the size distribution; surface charge; surface area; solubility; and others.

The amount of information needed to understand the properties, risks, and exposure routes of emerging technologies is likely to be more extensive, and expensive, than for conventional chemicals and product developers, without doubt, will face higher prices on toxicity and other tests until testing becomes routine.

Although one could argue that the tests and their costs are just another hurdle among many barriers⁴ to innovation, they will almost inevitably contribute to slowing down commercialization. Costs might be disproportionately high for small- and medium-sized enterprises and might force them to sell their license rather than try to commercialize it themselves. Since much innovation in emerging technologies (nanotechnology and biotechnology, for instance) comes from small companies around the world, attention must be given to providing incentives for companies to do proactive testing of their products.^{4,25} A number of ways exist to do this. One could include extra funds to do Environmental Health and Safety (EHS)-related research in grants given through the Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer (STTR) program. The SBIR and STTR programs were set in place to ensure that small, high-tech, innovative businesses became a significant part of the federal government's R&D efforts and the programs are sponsored by eleven and five governmental agencies respectively. Until now they have awarded \$2 billion to small high-tech businesses.⁴³

Another possibility is to provide research, education, and technical guidance and support to small- and medium-sized companies, for instance, through establishment of a facility such as the Massachusetts Toxics Use Reduction Institute (TURI), which is mentioned and discussed by Rossi (Module 4) and Tickner (Module 3).

Testing and Alternative Methods to Generate Information

In the case of chemicals, using methods such as *in vivo* testing and QSARs to generate information are options. But for many emerging technologies, it is not the case. Often, we must apply current ways of testing for hazards and exposure in the workplace and/or in the environment. But the methods often were developed with other technologies in mind; their limitations become more apparent when applied to emerging technologies. It is sometimes unclear whether they are applicable or even directly misleading, and thus new methods must be developed.

Many current test procedures are based on the assumption that mass is a good metric for establishing a dose-response relationship, but it seems not to be the case with nanomaterials.^{44,45} Further, a number of the current methods fall short when it comes to materials that are less soluble in water than the substances on which the test protocols were originally designed.⁴⁵ Other issues are how to measure not only concentration by mass, but also other characteristics such as size, surface chemistry, surface area, and surface charge, in the air of a workplace setting, in wastewater, and in the environment. In many cases, science does not know whether current methods work or are even applicable to emerging technologies such as nanomaterials.

The same is true of “alternative methods” like QSARs and exposure models. For many methods, one needs basic background data on the nature and properties of emerging technologies in order to develop and validate alternative methods.

Another pathway is to use genomics and proteomics to identify and assess adverse effects and exposure to nanomaterials through changes in the expression of specific genes and proteins in cells, if patterns between key genes and exposure to nanomaterials can be identified.

Government’s Options for Generating Information

All four options listed by Denison are available for governments in the case of emerging technologies, and many of the pros and cons of each of the individual options as well. With that said, the nature of the pros and cons differ substantially from option to option and is something that decision-makers will have to consider when they decide how to generate information about a given technology. For instance, the level of demand on government and the level of transparency differ substantially between the government collecting and generating information itself (Denison’s option 1) or requesting that information be provided voluntarily by companies (Denison’s option 3). If the government decides that it needs to collect and generate information itself, resources and expertise need to be allocated to the job, however, the information generated in most cases will be publicly available, thus ensuring a high level of transparency. On the other hand, if the government asks companies to voluntarily provide information about EHS issues, fewer resources will have to be allocated to oversee the submissions; however, in many cases, the information generated will have to be classified as CBI (Confidential Business Information) in order to get companies to participate in the voluntary program. See Table 1 for a comparison of the various policy options described in the module by Denison applied to emerging technologies with various criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution) and transparency.

TABLE 1 A Comparison of the Various Policy Options Described in the Module by Denison Applied to Emerging Technologies

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Generating Information	Gov. collect generates info	Low	High	High	High
	Gov. requires producers and users to report	Low	Low	High	High
	Gov. request voluntary reporting and provides incentives to do so	Low	Low	High	Low
	Gov. helps develop market incentives	Low	High	High	Low

Note: The higher the column the better the option fulfills the criteria.

EVALUATION AND PRIORITIZATION OF EMERGING TECHNOLOGIES – POLICY OPTIONS FOR STATES AND THE FEDERAL GOVERNMENT

In the case of emerging technologies as well as that of many chemicals, large gaps exist in knowledge about the risks for humans and the environment and that situation probably will continue for some time. Past questions about the risks of emerging technology, we also note, often have been raised initially only after the technologies have been commercialized and after workers, consumers, and the environment have been exposed to dangers and, sometimes, been harmed substantially.

As Denison (Module 1) points out, data derived from existing and alternative methods can be used to screen or prioritize chemicals for further scrutiny or management. The same is true in the case of emerging technologies. The hazard information available on the chemical composition of the nanomaterial in question is a logical starting point for screening and prioritizing, although it is important to remember that there is more to nanomaterials than their chemical composition, and hence nanomaterials should not be considered safe based on safety information related only to the bulk material.²⁵

In regard to screening options mentioned by Tickner (Module 3), the optimal solution seems to be some combination of the three options. Screening on the basis of existing data and known properties (Tickner’s option 3) has limitations in emerging technologies due to their unique new properties, as already mentioned. For agencies to provide tools to undertake regulatory or voluntary screening (Tickner’s option 1) on emerging technologies and/or materials seems not to be a realistic option in many cases since no one knows whether existing tools actually work.⁴⁵ It is especially true in the early stages of the development of a technology. This is not to say that the validation and development of such screening tools should not be pursued, but that it cannot be done by local, state, and federal agencies alone. It must be done in collaboration with industry, academia, and other stakeholders and requests or requirements that industry submit information or undertake screening (Tickner’s option 2) seems to be a key to obtain relevant up-to-date infor-

mation. Collaborating with industry and academia is key since they study, characterize, and have access to basic information to do environmental, health, and safety screening and testing.

Ideally, evaluation and prioritization should be done at various development stages, starting when the technology is still in basic R&D. As proposed by Environmental Defense and DuPont in the case of nanomaterials, periodic re-evaluation and re-prioritization should be done when the technologies move into the next development stage and as new information emerges. At a minimum, it should happen when it reaches: 1) prototyping; 2) pilot testing; 3) test marketing; and finally 4) full-scale commercial launch.⁴² Especially during the early stages, any evaluation and prioritization should be based on both preliminary hazard characteristics and a preliminary assessment of where the highest level of exposure of current and potential uses is going to occur across the lifecycle. The evaluation and prioritization will help realize gaps of knowledge and research needs and, optimally, produce more information as the technology matures. Thus, any emerging technology that reaches the marketplace would have been evaluated and prioritized six times for new evidence about inherent hazards and potential current and future uses and exposures.⁴²

The model for evaluation and prioritization that is most relevant for any given emerging technology depends on its nature. In the case of nanomaterials, the generic scheme outlined by Muir and cited by Tickner seems helpful. One major challenge with nanomaterials is that their risk depends on the chemical and physical characteristics of the nanomaterial (chemical composition, size, shape, surface characteristics, and so on); the location of the nanostructure in the system (in the bulk, surface bound, free particles, particles suspended in a liquid, and so forth); the route of exposure (inhalation, ingestion, dermal, or injection), and its fate and behavior in the environment and biological systems.

In the case of nanomaterials, the highest level of potential hazard exposure currently seems to be when the material takes the form of free particles for workers and particles suspended in liquids or creams for consumers.⁴⁶ Some consumer products, sunscreens for one, directly expose consumers to the nanomaterials in the products. In Muir's scheme, these products fall into the category of controlled use and direct exposure. Other nanoproducts use nanoparticles suspended in a solid, for instance, various golf balls, baseball bats, badminton bats, and other sorts of sports gear. In Muir's scheme, these products fall into the category of product ingredient, a closed system, and outdoor consumer use. By using the scheme, it seems obvious that products with dispersive and indoor use and direct exposure should get a higher priority than products that are controlled and used outdoors in a closed system. Filling out Muir's scheme as a part of the evaluation process at each stage of the developmental advancement of the product, from basic R&D to final commercial launch and eventual disposal, could help agencies prioritize. However, in doing so, it is important to focus on every stage of the lifecycle and not only on exposure during use of the product.

Evaluation and prioritization based on the inherent hazard characteristics, such as persistency, bioaccumulation, and toxicity, probably would have to be based on chemical composition in the case of nanomaterials, although other characteristics are important as well. They include, for instance,

surface chemistry. But science currently does not know enough yet to evaluate and prioritize these additional characteristics. If the chemical composition is known to be hazardous and there is a high level of potential exposure, then those factors might lead to a higher prioritization, whereas if the chemical composition is known to be harmless and there is a low level of potential exposure, they might lead to a low prioritization. Ultrafine particles become more hazardous the smaller their size so another possibility is to use size rather than chemical composition as a way to prioritize. One also could use analogies between crystalline silica, talc, titanium dioxide, or carbon black for which more is known, such as suggested by Greenwood.²⁵

However, as Tickner stated, it is important to remember that although initial screening processes can be used to prioritize, initial screening processes should not lead to determinations of safety, given the lack of knowledge about key hazard properties of nanomaterials.

See Table 2 for a comparison of the various policy options described in the module by Tickner applied on emerging technologies considering these criteria: cost effectiveness, demands on

TABLE 2 A Comparison of the Various Policy Options Described in the Module by Tickner Applied to Emerging Technologies

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Evaluation and Prioritization	Provide industry the tools to do screening	■	■	■	■
	Require industry to submit info or undertake screening	■	■	■	■
	Gov. screening based on existing data	■	■	■	■
	Gov. doing rapid/detailed substance assessment	■	■	■	■
	Gov. agency doing rapid classification/prioritization	■	■	■	■
	Provide tools to industry to do substance assessment	■	■	■	■
	Gov. initiates authorization requirements	■	■	■	■
	Gov. develops regulatory risk management programs based on the results of the screening and prioritization	■	■	■	■
	Gov. issues list of high and lower concern and develops voluntary substitution programs	■	■	■	■
	Gov. initiates voluntary industry self/classification challenge to self/classify and reduce use	■	■	■	■

Note: The higher the column the better the option fulfills the criteria.

government, performance for achieving safety goals (information, evaluation, substitution), and transparency.

SUBSTITUTION, ALTERNATIVES ASSESSMENT, AND EMERGING TECHNOLOGIES

A key element in the evaluation and prioritization process of chemicals is the question of substitution and the results of alternatives assessment. The definition of substitution of chemicals cited by Rossi* also would be applicable to many emerging technologies, including nanomaterials and biotechnologies. Although it might not make sense to discuss substitution in nanotechnology, biotechnology, and stem cell research, it does make sense to talk about substitution for individual materials and applications of, for instance, nanomaterials. A good example is the use of nano-sized diamond powders as alternatives for silica-coated Cadmium Selenide quantum dots for which toxic ions might be released during diagnosis and treatment.⁴⁷ However, a key issue is how to determine whether one material and its application is indeed safer for workers and the environment along the lifecycle of the material compared with another material. It is especially problematic in cases where not much is known about the two materials, applications, and/or processes being compared (see Rossi, Module 4).

There is no reason why the process of substitution listed by Rossi should not apply to emerging technologies like nanomaterials. With that said, many reasons to do substitution probably would be based on what is currently known about the bulk materials, even though other aspects such as surface chemistry, are known to be additional determinants of risks of the individual nanomaterials. Another reason might be the wish to eliminate toxic substances in the process of manufacturing nanoscale materials.⁴⁸

Obtaining information about the incorporation of emerging technologies in specific products has repeatedly been a controversial issue in manufacturers' efforts to bring such products to market. One reason has been manufacturers' efforts to keep their business information confidential. It is important to note the distinction between the public authorities obtaining information versus the public and other stakeholders getting access to information. The public authorities often have access to more information than the public does and past controversies have mainly focused on the public and other stakeholders not having access to important risk-related information.

Obtaining information is of key importance for emerging technologies as well as for chemicals for a number of reasons.

First, if it turns out that there are adverse environmental and health effects related to use of the product, it is vital that governmental and federal agencies know what was in the product so that

* "The replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organizational measures."

the culprit can be identified immediately and exposure can be limited (for this and other uses as well). This stance should be the case whether it is based on emerging technology or not. Second, it is important to know the composition of the products to ensure that using emerging technologies indeed adds benefits to society; why would anyone want to take even the slightest risk if there are no benefits associated with it? In the past, even well-meaning and clearly necessary “technological fixes” have led to unforeseen and unintended adverse effects on human health and the environment. CFCs and ozone depletion is a good example. CFCs originally were developed to be a safe substitute for fluids such as ammonia, methyl chloride, and sulphur dioxide in refrigerators. These substances are toxic, flammable, or corrosive. CFCs seemed like a useful substitute since they have great chemical stability. Further, they are almost entirely non-toxic and non-flammable. It later turned out, however, that they were so stable that eventually they ended up in the stratosphere and depleted the ozone layer.⁴⁹

Stories like this warn us about easy “technological fixes” and, although unforeseen risks of implementing emerging technologies cannot be avoided entirely, an impact analysis and stakeholder analysis and consultation can help identify potential adverse outcomes of implementing new technologies. Such openness brings different perspectives and opinions into and thereby reduces the dangers of unintended consequences.⁵⁰ In addition, different methodologies exist to identify potential unintended consequences. They include trade-off analysis⁵¹ and work-environment impact assessment.⁵² Some risks from emerging technologies also are bound to come as surprises resulting from sheer ignorance, such as in the case of CFCs. Although they seem almost impossible to avoid, adverse impacts of risks can be minimized by looking for “red flags” and “early warnings” and reacting proactively to them.⁵³ By exploring and implementing a range of preventive options, including multiple perspectives in decision-making processes; using a multi-disciplinary scientific lens and systems perspective to examine the risks of emerging technologies; and developing methods to monitor for “red flags” and “early warnings,” adverse effects can be minimized or avoided.⁵⁴

A third reason why information is important is to ensure that emerging technologies are not misused to make unreasonable claims and that they are not used in false marketing schemes. As Rossi mentioned in the case of chemicals, the purpose of adding emerging technologies to, for instance, consumer products is unclear, as is the amounts in which they are employed. The consumer nano-inventory established by the Project on Emerging Nanotechnologies of the Woodrow Wilson International Center for Scholars now shows more than 500 products claiming to entail nanomaterials or based on nanotechnology. The manufacturers promise benefits from using these products and at times refer specifically to “nano” as the provider of the benefits. But it is unclear whether the products actually are based on nanotechnology or whether adding the term “nano” is just used as a marketing scheme. Further, the proclaimed benefits are unclear and it is questionable whether it is necessary to add nanomaterials to or use nanotechnology at all in many consumer products. A consumer group in Korea found little to no improvement in effectiveness after producing a washing machine claiming to use nano-silver as an anti-bacterial agent.⁵⁵ In the U.S., *Consumer Reports* made a similar finding when testing stain-resistant Nano-Tex slacks and nano-waxes.⁵⁶

Given the fact that the benefits of adding nano-silver are uncertain and that it is toxic to the environment, it seems that the costs outweigh the benefits, as may be true in other cases as well.

Such violations risk giving the emerging technology a bad name without justification. Recently, a protective glass and bathroom sealant known as “Nano Magic” was recalled in Germany after approximately one hundred consumers experienced severe breathing problems using it. The incident has been seen as an early warning, a “wake-up” call, for nanotechnology and has temporarily led to a greater focus on the potential health and environmental threats of this new technology. It later turned out that the product did not entail any nanoparticles,⁵⁷ however, one major issue was that neither the German government nor the manufacturer knew what was in the product. Cases like this one could potentially shape people’s perception of emerging technologies and undermine public trust in the government’s ability to protect them.

See Table 3 for a comparison of the various policy options described in the module by Rossi applied on emerging technologies for these criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution), and transparency.

TABLE 3 A Comparison of the Various Policy Options Described in the Module by Rossi Applied to Emerging Technologies

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Alternatives Assessment	Chemical use information	■	■	■	■
	Chemical hazard data and classification	■	■	■	■
	Supply-side options	■	■	■	■
	Selections policy	■	■	■	■
	Multi-attribute options	■	■	■	■

Note: The higher the column the better the option fulfills the criteria.

FACILITATING AND ENSURING THE AVAILABILITY OF INFORMATION ON EMERGING TECHNOLOGIES UP-AND-DOWN THE SUPPLY CHAIN AND OTHER INTERESTED PARTIES

Massey (Module 2) argues that “sustainable chemicals policy requires the timely flow of accurate information to the actors who make decisions about chemicals.” Actors include chemical manufacturers or suppliers, downstream users of chemicals, policy-makers, workers, and members of the public. In the case of emerging technologies, flow of accurate information is of key importance as well for a number of reasons. The public and other stakeholders need access to accurate information in the process of deliberation over the acceptability of a given emerging technology, its risks, and how to respond to the risks.

Massey mentions a number of disincentives for the free flow of information among manufacturers, downstream users, and the third-party stakeholders in the case of chemicals. They include competition among manufacturers; confidential business information; liability; and supply chain dynamics. These disincentives are applicable to emerging technologies as well. Companies manufacturing nanomaterials compete in exploring and exploiting the various unique properties that materials have at the nanoscale and in many cases the service they are commercializing is a unique combination of these properties. So there is definitely a disincentive for companies to reveal this information to other manufacturers. It is unfortunate that it is access to information about the same unique properties that one needs to do risk assessment. Although it is important to protect confidential business information, it should not be done at the expense of protection of health and the environment.

In some cases, business is required to submit basic information to public regulatory agencies before commercialization. But it is one thing for agencies to obtain information about the content of products and another thing entirely if they provide the information to consumers or other interested parties.

In many cases, such information will almost automatically be classified as confidential business information (see Denison, Module 1) and hence it is impossible for downstream users and any third party to obtain information about the nature of the emerging technologies they may use. In the limited number of cases in which the U.S. EPA has received premanufacture notice on nanomaterials, almost all of the information is classified as confidential. It ranges from the person and company submitting the information, impurity and CAS registry number, synonyms and trade names, to byproduct, first 12-month production volume, use information, site of operation, number of workers exposed and duration of activity, environmental release and disposal. In some cases, even the Material Safety Data Sheets may be classified as confidential.⁵⁸⁻⁶⁴

Some claims of CBI seem unreasonable and providing wider access to at least some information seems to be an important step in facilitating the availability of information up-and-down the supply chain and to other interested parties. At a minimum, information made publicly available for chemicals under REACH — name; classification and labeling; physicochemical data, including information on pathways and environmental fate; results of each toxicological and ecotoxicological study; any derived no-effect level or predicted no-effect concentration; guidance on safe use; and, for some chemicals, analytical methods for detecting direct human exposures or discharge of the chemical to the environment—should be made available in the case of emerging technologies, including nanomaterials.

Disincentives such as liability and supply chain dynamics are very relevant in regard to emerging materials and the question becomes what can be done to eliminate these disincentives? Recently, Davies⁶⁵ suggested that the two be combined in the case of nanomaterials so that the insurance industry would refuse to insure any nanomanufacturer who did not adopt some oversight framework such as the one recently proposed by Environmental Defense and DuPont (see Appendix A for a summary), which urges companies to share not only information, but also insight into

the basis of risk assessment and management decisions with “[o]ther companies within the supply chain, including those involved in managing waste from the manufacture, use, or disposal of the material or product.”⁴²

Just as International Flavors and Flavorings Inc. had guidelines to protect its workers in the case of diacetyl, mentioned by Massey, many companies working with nanomaterials do so as well. Some companies treat all nanomaterials below a 100 nm as hazardous materials as a precautionary measure, but as with International Flavors and Flavorings Inc., the guidelines are not always passed on to downstream users. One way to communicate health and safety throughout the supply chain is MSDSs; however, as in the case of chemicals, companies are not required to do separate MSDSs for nanomaterials and those that report on nanomaterials have serious limitations — they may treat nanomaterials the same way as they treat their bulk chemicals, although properties may differ substantially.⁶⁶

Providing consumer and other downstream users with information in the form of labels has been controversial in the past and is likely to be contentious for emerging technologies as well.²⁵ Some of these technologies are seen as good marketing schemes, as mentioned earlier. It seems to have been the case in the early development of both nuclear power and nanotechnology that everything seems to be better when it says “atomic” or “nano;” the opposite seems to have been the case with food irradiation and genetically modified crops. The issue of whether to label products containing or processed by emerging technologies keeps coming up. For food irradiation and genetically modified crops labeling requirements eventually were implemented (at least in parts of the world) with the intention to provide consumers a choice, although opposition was fierce.

As Massey (Module 2) and Rossi (Module 4) mention, governments can facilitate the availability of information on the chemical constituents in products by requiring warning labels on products that contain chemicals of high concern. It is not possible to classify many emerging technologies as safe or as “high concern” in the absence of data so requiring a warning label seems out of the question. However, that does not eliminate all labels.

When governments decide to let manufacturers market products using emerging technologies with or without pre-market EHS testing, government could facilitate information by having a label that states that: 1) the product contains or is based on an emerging technology; 2) that there is limited or no environmental, health, and safety information available at the time; and 3) a telephone number where to call should adverse effects be observed.⁶⁵

There has been an increasing call for labeling of consumer products containing nanomaterials from various stakeholders. *Consumer Reports* has called for labeling, asking consumers to investigate the products they buy; asking them to learn more about nanotechnology; and to contact the FDA and researchers.⁵⁶ Further, the ETC Group had an on-line competition on who could come up with the perfect “Beware of Nanotechnology” warning label and received 400 proposals.⁶⁷ Given the calls for labeling, one could imagine that some companies might voluntarily start labeling their products or one would advertise that they do not use nanomaterials in their products.

See Table 4 for a comparison of the various policy options described in the module by Massey applied to emerging technologies with these criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution), and transparency.

TABLE 4 A Comparison of the Various Policy Options Described in the Module by Massey Applied to Emerging Technologies

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Ensuring Information flow through the supply chain	Require chemical suppliers to provide information on chemical properties	██████████	██████████	██████████	██████████
	Require toxics use reporting	██████████	██████████	██████████	██████████
	Require public disclosure of product ingredients and health effects	██████████	██████████	██████████	██████████
	Sponsor supply chain collaborations	██████████	██████████	██████████	██████████
	Create databases of information voluntarily submitted	██████████	██████████	██████████	██████████

Note: The higher the column the better the option fulfills the criteria.

CAPABILITIES NEEDED, IMPORTANT DYNAMICS, AND POSSIBLE MODELS

Kyle (Module 6) outlines the capabilities needed, important dynamics, and possible models for implementation of chemicals policy that would have to be put in place for emerging technologies as well as for chemicals. She lists: 1) keeping track of information; 2) developing procedures and methods; 3) conducting assessments that end with judgments; 4) disseminating and translating information and judgments for relevant audiences; and 5) enforcing required elements. Due to the nature of emerging technologies, new kinds of expertise might be needed within regulatory agencies and, in some cases, they would have to be built from the ground up. Sometimes it will be necessary to find the right combination of regulatory expertise in well-established fields, such as physics, chemistry, technology, and (eco-)toxicology. The challenge will be to establish truly interdisciplinary research units and agencies. This seems to be the case with nanomaterials; however, the current lack of staff with in-depth understanding and training in nanotechnologies in agencies is a potential problem.⁶⁵ With other technologies, no established field of research is available that ensures that broader health and safety considerations are included in their development and, hence, regulatory bodies may have to fund and train in new disciplines by establishing undergraduate and graduate courses.

Tracking information may be even more complicated in the case of emerging technologies than in the case of chemicals. It may not be at all clear from the outset what kinds of information should be gathered. This circumstance means that many emerging technologies require identification of key hazard properties to build a database. Information is likely to be required beyond what is

accessible from traditional sources for more well-known technologies. In addition, the fast pace at which emerging technologies develop in their infancy puts extra difficulties on the job of gathering and tracking key information. Information gathering must be broad in scope until key properties — inherent hazard, exposure pathways, protection methods, and others — have been established. For many technologies, the information will not be available in the early stages of development. These circumstances increase the costs and burden on government. But the effort can reward since playing catch-up is costly and burdensome as well.

According to Kyle, a system for chemicals must track the status as follows: a) data and testing requirements; b) screening requirements; c) evaluation; d) any use restrictions or limitations on use; e) pending requirements for additional data, assessment, or action; f) uses reported up and down the product chain. For emerging technologies, a number of basic information requirements also would be of great value should it turn out that risks exist that are associated with the technology. Information that could be gathered without knowing the risk includes number and location of research units looking into the emerging technologies; raw materials used for the research; how emerging technologies are used; number of people potentially exposed; production units; commercially available products; and so forth. Production units or volumes per producer and overall would be of great interest, for instance, in regard to nanomaterials since that information could suggest the number of people potentially exposed. Information about production settings and methods, nanomaterials properties and how they are determined, and risk management practices in place also would be relevant since these factors have been found to influence the overall hazard, exposure patterns, and risk of some nanomaterials.⁴²

Whether testing for hazards is a feasible option will depend on the nature of the emerging technology. There is a big difference in testing for the hazards of nuclear power at individual plant sites compared to having to test for the hazards of the great variety of nanomaterials and biotechnologies in a laboratory setting or having to test nano- and biomedicine in humans and genetically modified crops in field trials. Nanotechnology and biotechnology involve a great range of technologies, methods, materials, material properties, and applications and the decision to test for hazard will have to consider such issues. One way is to focus primarily on testing for the hazards of technology to which most people are exposed or the ones for which environmental exposure is the most likely now and in future. Besides the fact that existing methods of testing hazards need to consider the sheer number of possible combinations of, for instance, nanomaterials and related properties, it also would mitigate against a single-nanomaterials or genetically modified organisms (GMOs) testing strategy. Uncertainties in predicting exposure and the variable nature of exposure patterns over time and space mean that solely relying on exposure to determine whether to develop any hazard data seems risky. A new generation of hazard and exposure information is needed to decide whether exposure is significant.

See Table 5 for an evaluation of the various policy options described in the module by Kyle applied to emerging technologies for these criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution), and transparency.

TABLE 5 A Comparison of the Various Policy Options Described in the Module by Kyle Applied to Emerging Technologies

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency	
Ensuring capabilities	Assessing data quality	Laboratory accreditation program	■	■	■	■
		Verification by a different laboratory	■	■	■	■
	Assessing data	Better standardize testing requirements + comparable protocols	■	■	■	■
		Vest the responsibility in an independent agency	■	■	■	■
		Create a health protective default in place until assessments are completed	■	■	■	■
	Disseminating and translating data + judg. for all audiences	Design a largely self-executing system that translated submitted data in understandable entries	■	■	■	■
		Have separate labeling requirements for consumer products	■	■	■	■
	Ensuring capabilities	Enforcement	Administrative penalties	■	■	■
Civil penalties			■	■	■	■
Criminal penalties			■	■	■	■
Institutional forms		Create a single purpose chemicals agency	■	■	■	■
		Developing a program within an existing public agency	■	■	■	■
		Creating a hybrid organization combining public agencies and research entities	■	■	■	■
		Networking different entities together	■	■	■	■
		Creating a multi state entity or consortium	■	■	■	■

Note: The higher the column the better the option fulfills the criteria.

ENSURING THAT EMERGING TECHNOLOGIES ARE GREEN AND SUSTAINABLE

Although much of what Geiser and McPherson (Module 5) write on options for innovation and green chemistry is directed toward chemicals, there is no reason why many of the points they make should not be equally applicable to many emerging technologies. Besides green chemistry, a number of other more or less well-established technologies have gone “green” — for instance, green engineering, good electronics, and green nanotechnology. Although, the individual principles of green chemistry, engineering, and electronics, vary in wording, they basically boil down to the same vision, which is to promote sustainable development by identifying clean technologies and minimizing human health and environmental impacts at the early stages of development.⁴⁸ This issue is not only relevant for more well-established technologies, but also applies to emerging technologies. When compared to well-established technologies such as chemicals, the emphasis on basic principles for sustainable development, green chemistry, and green engineering, should be stressed even more when the benefits and risks are unclear (as they are with most emerging technologies) since the principles potentially could safeguard us from unpleasant surprises. One emerging technology where basic principles are being adopted more often is in the field of green nanotechnologies.⁶⁸ Recently, the Project of Emerging Nanotechnologies of the Woodrow Wilson International Center for Scholars published a report on green nanotechnology by Schmidt⁴⁸ urging the U.S. government to develop a strategy for stimulating green nanotechnology. The report is full of good examples of green nanotechnology. For one, it includes James E. Hutchison’s development of a way to synthesize nano-gold in a cheaper and faster way without the use of flammable and explosive solvents.⁴⁸

By adopting the basic principles of these “green fields,” in the development of emerging technologies at the earliest possible stage (that is, the design phase), one could help ensure that all emerging technologies are “green” from the outset so that ideally the distinction between “green” and conventional technologies eventually will disappear. The question is, what regulatory or other measures would have to be in place in order to encourage the “green” alternative to a given technology at an early stage? Although some of the challenges are of a scientific and technical nature,⁶⁸ it is well-recognized that governments play a considerable role in every stage of development from research to building its early infrastructure to sorting out its social repercussions.⁶⁹ Governments do so through a number of mechanisms, such as providing legal and public institutions that discourage and encourage certain paths of innovation; funding basic research and infrastructures with no short-commercial value; and by providing subsidies. Most of the funding currently used in nanotechnology R&D stems from public sources. Governments should help to guide and shape the future path of innovation in the direction of sustainable development to secure greater overall individual and societal benefits.

See Table 6 for a comparison of the various policy options described in the module by Geiser and McPherson applied to emerging technologies for these criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution), and transparency.

TABLE 6 A Comparison of the Various Policy Options Described in the Module by Geiser and McPherson Applied to Emerging Technologies

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Green Innovation	Research and development support	■	■	■	■
	Technical assistance	■	■	■	■
	Targeted procurement	■	■	■	■
	Economic policies	■	■	■	■
	Regulations promoting green chemistry	■	■	■	■

Note: The higher the column the better the option fulfills the criteria.

CONCLUSION

In Tables 1–6 we used four criteria of cost effectiveness (including speed of implementation and putting burden on industry), demand on government, performance, and transparency to evaluate the various policy options in the light of the policy options listed by the authors in their respective modules on chemicals. In Table 7 (page 227), we have tried to evaluate the various policy options available in regard to emerging technologies (listed in section 3.1) in the light of the same four criteria.

When looking at Table 7, options such as banning, banning some applications, a moratorium on R&D and/or commercialization, in general, rank high in regard to cost effectiveness. Various reasons account for it, including that some options are assumed to be faster to implement compared with, say, an incremental approach or developing a new regulatory framework. In addition, imposing a ban or a moratorium on both/either/or R&D and commercialization puts a burden on industry due to lost investments (in the case of a ban); lost income while EHS data is generated, and a potential mandatory obligation to generate EHS information (in the case of a moratorium).

Options such as bans do not normally put much burden on government besides the question of how to enforce such a measure except in cases of enabling technologies that are applied in a large number of products, methods, and settings. Implementing a moratorium either on R&D and/or commercialization puts more demand on government since it will have responsibility for generating EHS information while the moratorium is in place or must provide incentives for companies to do so.

TABLE 7 Policy Options for Emerging Technologies Evaluated in the Light of the Four Criteria: Cost Effectiveness, Demands on Government, Performance for Achieving Safety Goals (Information, Evaluation, Substitution), and Transparency

Policy Option	Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Ban on R&D and commercialization	High	Low	High	Low
Ban on commercialization	High	Medium	High	Low
Moratorium on R&D and commercialization	High	Medium	High	Low
Moratorium on commercialization	High	Medium	High	Low
Initiating and funding EHS studies and collecting data	High	Medium	Low	Low
Voluntary programs	High	Medium	Low	Low
Incremental approach	High	Medium	High	Low
New regulatory framework	High	Medium	High	Low
No additional regulation	High	Low	Low	Low

Note: The higher the column the better the option fulfills the criteria.

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. For instance, the ban on supersonic transport in the U.S. was able to prevent adverse impact on the environment. It is important to remember though that reaping the benefits of the technology is not included in the criteria used to evaluate the various policy options in this analysis. This ignores the possibility of missed opportunities that might have led to environmental and health benefits while a ban or a moratorium is in force. In bio- and nanotechnology in the field of medicine, benefits are expected to be substantial and should not be ignored when considering bans or placing a moratorium on commercialization.

The European Parliament's Scientific Technology Option Assessment (STOA) committee has published a study on the role of nanotechnology in chemical substitution of hazardous substances. STOA concluded that although nanotechnology cannot presently contribute in an exceptional manner to a large increase in the substitution of hazardous chemicals, its long-term contribution to substitution is manifold and incremental.⁷⁰ An example of an "incremental substitution" of hazardous chemicals is the work by Zhou and his group at Headwater, Inc. Zhou recently won the Green Chemistry award for his discovery of a way of manufacturing hydrogen peroxide using

a palladium-platinum catalyst based on nanotechnology that requires no hazardous materials and produces no byproduct except water. Further, hydrogen peroxide is a safer alternative to chemicals such as chlorine and chlorine-containing bleaches and oxidants.⁷¹ The substitution of hazardous chemicals by the use of emerging technologies, such as nanotechnology, is a potential opportunity lost by implementing options such as bans or moratoriums by default.

In regard to performance in achieving the overall goal (the third criteria), the policy options that score the highest are the incremental approach (that is, adapting existing legislation, technical guidelines, codes of conducts, and so on) and developing a new regulatory framework. They generally score high because decision-makers can potentially design them to meet the needs identified for, say, generation of information, promoting alternatives assessment, green technologies, and others. The down side with these options is that they put great demand on government. In the case of adapting existing legislation, it is no small task to apply it to, for instance, nanomaterials, due to the sheer number of amendments needed.^{65,66,72} Designing a new regulatory framework that is effective and that works in practice requires much effort from already under-funded government agencies that also must take into account the political and/or interagency bureaucracy; stakeholder concerns and interests; public participation; and development of technical support and guidance.^{65,73}

Although many of the issues addressed in this module and the policy options outlined above 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. The recent development in the recognition of the problems associated with climate change in the U.S. stands as a good example of how much impact local communities, individual states, and collaboration between states can have on shaping the debate on a truly global issue.

Having local and statewide bans and moratoriums can send strong signals. Such was the case with the moratorium implemented in the late 1970s on recombinant DNA research in Cambridge, Massachusetts. The most proactive research facilities and companies might see local regulatory oversight as a reflection of a mature understanding of a technology and a reason to establish themselves in a particular area. As has been reported in the case of recombinant DNA though, the risk is real that they might move their research facilities, investments, and workplaces.⁷⁴

Another option is to ask companies to submit EHS information. The city council of Berkeley has pursued this approach on nanomaterials, issuing 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. Although it has been criticized, the approach has led to a much needed debate about whether and how nanomaterials should be regulated and the case provides a good example of one approach that local governments can take when they face emerging technologies.

A third approach is for local governments and/or states to have an active expert and stakeholder deliberation over a longer period of time. This approach is currently being pursued in Cambridge, Massachusetts, in decisions about nanomaterials.

Whereas the action of local governments can have some national impact on the debate about how to approach and regulate emerging technologies, states can have a huge impact on policy development, the path of innovation, and the success or failure of a technology. The promotion of biofuel and stem cell research in California provides a huge push for research and development of these emerging technologies which affect more than just the citizens and industry of California. Another example of the huge impact states can have on emerging problems is the interstate collaboration termed the New England Climate Coalition, which was formed in 2003 by the governors of all six New England States in addition to New York, New Jersey, and Delaware to create a regional program to reduce greenhouse gas emissions.

Some of the larger states and potential coalitions of states have nearly all of the same options available as the federal government because of their access to resources. While local governments hardly have the option or the expertise to generate EHS data themselves, it is certainly an option that state governments potentially could pursue either alone or in collaboration with other states. The state of California initiated EHS-related research in the case of MTBE that finally led to its ban first in California, then in other states, and finally on a federal level.^{75,76}

One significant way that states could influence the development and emergence of green technology is by requiring that EHS issues are considered and research is stipulated when they provide funding to develop emerging technologies in their states. Officials in Massachusetts, Pennsylvania, and California have provided between \$60 million and \$95 million each for research on and development of nanotechnology and other emerging technologies.⁷⁷⁻⁷⁹

APPENDIX A

Summary of the Nano Risk Framework Proposed by Environmental Defense and DuPont Corporation

In early 2007, the environmental group Environmental Defense (ED) and DuPont Corporation released for public comment a draft Nano Risk Framework, describing a process for ensuring the responsible development of nanoscale materials.⁴² The framework was expected to be finalized in summer 2007, after which it could be freely used by companies and other organizations. The intent of the framework is to define a systematic process for identifying, managing, and reducing potential environmental, health, and safety risks of engineered nanomaterials across all stages of a product's lifecycle. It is meant to offer a voluntary approach to facilitating the responsible development of nanomaterials by companies, private and public research institutions.

The framework is designed to be used iteratively at different stages of development advancement (that is, basic R&D, prototyping, pilot testing, test marketing, and finally to full-scale commercial launch) and as new information becomes available. Explaining all elements of the framework is beyond the scope of this module but, in short, the framework consists of six distinct steps:

1. Develop a general description of the nanomaterial and its intended uses, based on information already available and identify analogous materials and applications that may help fill data gaps in this and other steps;
2. Develop profiles of the nanomaterial's properties, inherent hazards, and associated exposures considering all the elements of the nanomaterial's full lifecycle and considering that a material's properties, hazards, and exposures may change during the lifecycle;
3. Evaluate all of the information generated in the profiles and identify and characterize the nature, magnitude, and probability of risks of the nanomaterial and its application. Gaps in the lifecycle profiles should be prioritized and a decision should be made on how to address them;
4. Evaluate the available risk management options and recommend a course of action, including engineering controls, protective equipment, risk communication, and product or process modifications;
5. Decide alongside key stakeholders, experts, and decision-makers whether or in what capacity to continue development and production and document these decisions and their rationale and share appropriate information with the relevant stakeholders; and
6. Update and re-execute the risk evaluation regularly or as necessary to ensure that risk management systems are working as expected and adapt in the face of new information or conditions; document and share appropriate information with relevant stakeholders.⁴²

ED and DuPont have developed a system to help guide information generation and update assumptions, decisions, and practices as new information becomes available. At various stages in the product-development process, the draft document provides a worksheet to help participants: 1) organize, document, and communicate the information they have about their material; 2) to acknowledge that information is incomplete; 3) to explain how information gaps were addressed; and 4) to explain the rationale behind the user's risk management decisions and actions. However, the amount of information required in the framework is directly related to potential extent and degree of exposure of the specified application. ED and DuPont recommend that a broad range of stakeholders have access to the worksheet or summaries of it as products move into commercialization in order to facilitate ease of understanding.⁴²

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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.

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