

INTEGRATED CHEMICALS POLICY

Seeking New Direction in Chemicals Management

The European Union and its Member States are embarking on a fundamental restructuring of the policies that guide the management of industrial and commercial chemicals. This restructuring is the result of a broad critique on the limitations in existing chemicals regulations and the desire for an integrated, European-wide policy that protects human health and the environment. These new European policies will affect producers and users of chemicals outside of Europe. Therefore, the time appears ripe for a broad-scale, public discussion in the United States on how effectively current federal and state chemicals management policies are in protecting public health and the environment and supporting the development of safer and cleaner chemicals and products.



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The Problem of Current Toxic Chemicals Management



For many years in both Europe and the United States, there have been widespread public concerns about human exposure to toxic substances and the lack of information on how these exposures might affect health. In addition, over the past decade a series of public policy failures in Europe regarding contaminated food, biotechnology, increasing health threats such as cancer and asthma, and pollution of the Baltic and North Seas has led to a recognition of the inadequacies of current chemical management systems to protect human health and the environment.

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or health implications. The result is a growing body of evidence that links exposure to these materials and various adverse health effects. *For the large majority of chemical substances, however, there is little or no information on their health implications.* Studies conducted by both the U.S. Environmental Protection

Agency and the European Chemicals Bureau in the late 1990s highlighted the serious lack of information about the toxicity of some of the most used chemicals on the market today.

The U.S. Environmental Protection Agency found that less than ten percent of the approximately 2,800 high production volume chemicals (those produced over one million pounds per year) have a basic set of publicly available toxicity information; more than forty percent lack any toxicity information at all. Even less is known about chemicals produced in smaller volumes or mixtures of chemicals. Yet, this lack of

evidence of toxicity is often misinterpreted as evidence of safety.

International voluntary testing programs for high production volume chemicals and other chemicals of concern (such as those to which children might be exposed) are a step in the right direction, but are slow and insufficient to protect health and the environment. While data are being collected, the status quo—allowing exposure to continue—is maintained. Even when basic toxicity information is compiled it still must be fed into a regulatory system whereby the burden rests on government agencies to conclusively demonstrate the risks each individual substance poses to health or ecosystems before preventive action can be taken.

Quantitative risk assessment on chemicals—a tool used to determine whether a substance might be harmful—has been a slow process in which debates over narrow aspects of a substance's toxicity or exposure can result in years of delay before regulatory action occurs. Risk assessment processes have failed to examine the implications of exposure to multiple chemicals and are just beginning to address concerns over particularly vulnerable populations—such as children—and ecosystems. While collecting more data—on chemical toxicity, human body burdens and exposure—is critical to understanding how chemicals can affect human and ecosystem health, study alone will not prevent harm.

The regulation of chemicals in Europe and the United States 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. Current air, water, solid and hazardous waste regulations, and occupational health laws have had some successes in limiting exposures to toxic substances from manufacturing and disposal processes, but they do not address the entire life cycle of chemicals from production through disposal. For example, the regulations that require testing and assessment of chemicals that have come on the market since the 1980s have been generally regarded as effective in limiting risks posed by new chemical substances. But these regulations have failed to

address the risks posed by existing chemical substances, which constitute more than 99 percent by volume of chemicals on the market today. For these chemicals, which arguably pose the greatest risks to health and the environment, governments have been able to restrict their use only after it has been demonstrated that they are harmful to human health. 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.

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Limitations of Current Chemicals Management Policies

- Lack of regulatory programs that address chemical risks throughout a chemical's lifecycle;
- Lack of toxicity information, public data, and government attention to the large majority of chemicals in commerce,—existing chemicals on the market prior to the 1980s;
- Concern about exposures from unregulated chemicals used in a wide range of consumer products;
- The slow, resource intensive risk assessment process which places the burden on governments to demonstrate harm before preventive action can take place;
- Slow response to the growing information on the impacts of chemicals on ecosystems and health and emerging concerns such as endocrine disruption and the unique vulnerability of children;
- The long-term persistence and accumulation of many chemicals in ecosystems and humans;
- Continued use of chemicals with inherently dangerous properties such as known or highly suspected carcinogens, mutagens, and reproductive toxicants;
- The lack of funding for research and development of safer and cleaner chemicals, production systems, and products; and
- The lack of public confidence in chemicals and the chemical industry due to various incidents of chemical impacts.

This example demonstrates the need for integrated chemicals policies that ensure collection of data on chemical hazards and exposures, that lead to the development of safer alternatives, and that help avoid substitution to other potentially problematic substances.

EXAMPLE

Polybrominated Diphenyl Ethers

The polybrominated diphenyl ethers (PBDEs) provide an illustration of chemical management problems and solutions. PBDEs are a class of chemicals, structurally similar to polychlorinated biphenyls (PCBs), that have been used as flame retardants in textiles, plastics, electronics, and polyurethane foams since the 1960s. PBDEs are not chemically bound to the material which they protect, thus allowing their broad dispersal into the environment from products during use and disposal. Despite limited information about their toxicity (which appears to be qualitatively similar to that of PCBs) and information from the 1980s that the persistent and bioaccumulative PBDEs were entering the food chain, European governments only became concerned when Swedish researchers found that these substances were increasing exponentially in human breast milk. Recent research has found these substances in sediments, sewage sludge, crops, marine mammals, fish, bird eggs, terrestrial animals, human tissue and breast milk, and household dust.

The European response to PBDE risks has been more rapid than for most chemicals though it still took a number of years for European Union action to occur. Based on the evidence of accumulation in human milk, the Swedish government under-took aggressive efforts to encourage industry to stop using these substances, which resulted in a dramatic decrease in breast milk levels of PBDEs in Swedish women. The European Union has rapidly completed risk assessments on the PBDEs of greatest concern and in early 2003 passed a ban on the use of three PBDEs in electronic and electrical equipment. For two of the PBDEs, the ban was expanded to all products in February 2003 and it is likely that the third will be seriously restricted. Numerous companies, including electronic product manufacturers, have already phased out or are working to phase out the use of these chemicals in products. However, some electronic manufacturers have replaced PBDEs with another brominated fire retardant, tetrabromo bisphenol-a (TBBPA), which is also under increasing regulatory scrutiny in Europe due to worker exposure and potential health effects.

This example shows how unregulated chemicals used in everyday products can contaminate humans and ecosystems. Yet, it also shows how some governments can rapidly respond to chemical risks and how industry can innovate to develop and implement alternatives to achieve the same purpose in a short period. It demonstrates the need to carefully consider the inherent hazardous characteristics and potential exposures of substances before problems occur. It also shows the need for integrated chemicals policies that can lead to the development of safer alternatives and help avoid substitution to other potentially problematic substances.

ADDRESSING THE PROBLEM

Emerging European Approaches to Integrated Chemicals Management

The impetus in Europe for a broad integrated chemicals policy comes from several of its Member States—particularly Sweden, Denmark, the Netherlands, the United Kingdom and Germany—which, over the past decade, have developed their own chemicals policy initiatives. But the European Union is made up of fifteen Member States (soon to be 25) that are required to directly implement or translate legislation passed at the European Union level into national policy. Because trade in chemicals is international in nature, European legislation determines to a great degree what individual member states can do with respect to regulatory chemical restrictions and phaseouts. European member states with large chemical industries—such as the United Kingdom, Germany, and the Netherlands—as well as countries that have developed progressive chemicals policies since the 1990s—such as Sweden and Denmark—are placing pressures on the European Commission and its legislative bodies to ensure a new chemicals policy that fits their particular interests.



The Nordic countries of Sweden, Denmark, and Norway (not a European Union member)—have long set the standards for international chemicals policy debates. Their concerns over chemicals involve the contamination of waterways caused by persistent and bioaccumulative pollutants, as well as chemical exposures from everyday products. Two basic principles underlie the Nordic chemicals initiatives:

Substitution—the idea that if there is a safer alternative to a potentially harmful chemical, it should be used; and

Precaution—action should be taken even though the nature and magnitude of risks are not fully known.

These new policies involve a variety of regulatory and voluntary tools to reduce hazardous chemical risks, ranging from education and technical assistance, to taxes, procurement, and chemical phaseouts. Specific aspects of the policies include:

- A focus on products and product lifecycles for risk reduction. It is critical that chemicals policies address product exposures and be integrated with a product policy (i.e. producer responsibility).
- Rapid screening processes. Authorities are trying to use whatever information is available to build a profile of each substance's hazards and to prioritize potentially dangerous chemicals for reductions rather than waiting for complete information.
- Establishment of “lists of concern.” Several countries have established lists of chemicals of concern. In Denmark this is called the “list of undesirable substances.” Government authorities then work with businesses and procurement agencies to assist them in avoiding these chemicals.
- Phaseouts of harmful chemicals. Some national governments have set a series of political goals to phase out problematic chemicals and those that are unstudied.

In the absence of an integrated European-wide chemicals policy, many Member States are moving forward to implement voluntary and mandatory programs and to influence the development of the new European approach.

Member State policies involve a variety of regulatory and market-based tools to reduce hazardous chemical risks, ranging from education and technical assistance, to taxes, procurement, information, and chemical phaseouts.

- Development and adoption of safer products through clean technologies and substitution. Some countries are providing technical support and initiating demonstration projects on alternatives as critical steps in developing safer alternatives.

Other countries have also developed innovative programs. The Dutch government established its Strategy on Management of Substances in 1998 as a multi-stakeholder process to address hazardous substance risks. The Dutch, who have a long history of consensus-based approaches backed by strong enforcement, developed a system that places the responsibility on industry to undertake a “quick-scan” analysis of all chemicals by the year 2004.

This amounts to a qualitative risk assess-

ment, where the company uses available information to classify the substance’s level of concern based on its hazard profile and potential exposures and uses. Based on this classification, the government has established a series of action steps that industry must undertake ranging from phase-outs for the most dangerous and unstudied chemicals, to restrictions on uses of substances of lesser concern. The Dutch government is integrating this system into purchasing policy and is working with chemical manufacturers and users to undertake demonstration projects on chemical substitution.

In 1999, the United Kingdom issued its voluntary chemicals management policy proposal “Sustainable Production and Use of Chemicals: A Strategic Approach—the Government’s Chemicals Strategy.” This proposal sets targets for chemical testing and risk reduction decisions and establishes a Stakeholder Forum as a mechanism to advise the UK

Swedish Committee on New Guidelines on Chemicals Policy

One of the main goals of the 1999 “Swedish Environmental Quality Objectives,” which outlines 15 environmental quality objectives to be attained by 2020, is to achieve ‘a non-toxic environment.’ “The environment must be free from man-made substances and metals that represent a threat to health or biological diversity. This means that: the levels of substances that occur naturally in the environment must be close to background levels; and the levels of man-made substances in the environment must be close to zero.”

The Government Committee charged with implementing this objective concluded that all potentially harmful chemicals must have basic testing completed by 2010 to be allowed on the market; that policies to address chemicals must also address hazards associated with their use in products; and that certain chemicals with particularly harmful qualities should be phased out over time. These include:

- New substances that are persistent and bioaccumulative should not be allowed as chemical substances, in preparations, or finished products after 2005;
- Existing substances that are particularly persistent and bioaccumulative cannot be used in chemical substances, preparations, or products after 2010 (2015 for all other persistent and bioaccumulative substances);
- Substances that have been classified as known or highly suspect carcinogens, mutagens or reproductive toxicants should not be allowed in consumer products later than 2007; and
- The use of mercury and lead compounds (ammunition and sinkers), should cease by 2003 and 2008 respectively. The elimination of cadmium is already underway.

The Swedish Chemical Inspectorate (KemI) has developed elaborate methods to assess substitutes to ensure that they reduce risks.

government on the implementation of its chemicals policy. The Stakeholder Forum has developed a set of criteria to enable rapid identification of chemicals of concern, leading to implementation of risk management strategies proposed by industry. The UK Environment Agency and Health and Safety Executive have issued proposals to integrate chemicals management into their permitting and outreach efforts. Understanding the importance of downstream users of chemicals and retailers,

the government and non-governmental organizations have engaged such companies in undertaking voluntary chemicals policy programs to prioritize safer chemicals in their procurement practices. The UK Royal Commission on Environmental Pollution in June 2003 published a report on new chemicals policy recommending a more integrated approach to chemicals management, better monitoring, rapid screening of chemicals, and a greater focus on tools and drivers for substitution.

The Current European System— Successes and Limitations

The new European Union chemicals policy proposals build on, integrate and in some cases replace four pieces of European Union legislation on chemical substances and preparations that have been in place since the late 1960s. These include: The Dangerous Substances Directive (67/548/EEC); the Dangerous Preparations Directive (88/379/EEC); the Existing Substances Regulation (73/93/EC); and the Limitations Directive (76/769/EEC).

Some highlights of these pieces of legislation include:

- The requirement that manufacturers and importers of all new chemicals that have come into commerce since 1981 notify authorities and conduct basic toxicological testing and risk assessment prior to marketing.
- The requirement that manufacturers, importers, and distributors of chemicals and chemical preparations assess whether substances or preparations they are selling meet hazard criteria and if so to label the substance or preparation, including a danger symbol, standard phrases on the nature of the risk, and safety precautions related to risk.
- The requirement that European authorities undertake a process for data collection, priority setting, risk assessment, and risk management of existing chemical substances on the market after 1980.

- The establishment of marketing restrictions or bans on chemical substances, preparations, and products that could pose substantial risk to consumers. These pieces of legislation are supplemented by other pieces of European legislation on substitution of carcinogens and mutagens in the workplace and restrictions on chemicals of concern in cosmetics. The recently passed Waste from Electronic and Electrical Equipment and Restrictions on Hazardous Substances Directives require manufacturers to take back electronic and electrical equipment at the end of their life and restrict the use of several hazardous chemicals in the manufacture of these products. The 2000 Water Framework Directive, an overarching piece of legislation aimed at maintaining and



Several pieces of European legislation implement the concept of substitution—that chemicals of high concern based on their inherent properties or risks should be replaced with safer alternatives when feasible.

improving the aquatic environment (including ground water), establishes a process for prioritizing chemicals that present a significant risk to or via the aquatic environment and for classifying substances, such as persistent and bioaccumulative chemicals, as hazardous. For those

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substances of highest priority, the Directive requires the European Commission and Member States to achieve “the cessation or phasing out of discharges, emissions, and losses” within 20 years.

Current European legislation has been successful in obtaining data and review on new chemical substances, as well as labeling and classification of many substances and preparations in commerce. For instance, the Limitations Directive has resulted in restrictions of 42 substances and

groups of substances covering some 900 chemicals, including approximately 850 substances labeled as known or probable carcinogens, mutagens or reproductive toxicants. The Directive has established, in law, the concept that certain substances should be controlled on the basis of their inherent hazards.

While European countries have moved forward to require data on new chemicals and restrict some harmful substances, the approach has been piecemeal. Further, enforcement and monitoring of current European chemicals regulations—carried out at the Member State level—have been weak and sporadic. Moreover, current laws have failed to address the lack of data and to initiate preventive action of existing chemicals, due to the slow and contentious risk assessment and risk management processes that currently exist. All of this has resulted in a somewhat disparate and uncoordinated oversight of chemicals management across Europe.

Chemicals Currently Restricted or Banned in the European Union

The following is a list of some substances that are restricted in the European Union. These restrictions have been achieved through the Limitations Directive, the Restrictions on Hazardous Substances Directive, and other pieces of legislation directed at particular substances or classes of substances. Other restrictions have been undertaken at the member state level. Some of these restrictions relate to particular uses.

- Known and probable carcinogens, mutagens, and reproductive toxicants and preparations containing them, including cosmetics
- Lead in electronics
- Cadmium
- Polybrominated diphenyl ethers
- Copper chromate arsenic
- Tributyl tin
- Pentachlorophenol
- Creosote
- Hexachloroethane
- Short chained chlorinated paraffins
- Mercury in electronics
- Phthalate esters in small children’s products
- Hexavalent chromium in electronics and cement
- Nickel in jewelry
- Polybrominated biphenyls in textiles and electronics
- Azo dyes in textiles
- Organostannic compounds
- Trichloroethane
- Tetrachloroethane
- Nonylphenols in detergents and other products

A New European Union-Wide Approach Registration, Evaluation and Authorization of Chemicals (REACH)

Increasing concern that current EU chemicals policies do not provide sufficient protection led to a debate at the informal European Council of Environment Ministers meeting in April 1998. Based on this meeting, the European Commission prepared an analysis of the functioning of existing regulatory instruments for chemicals management. In 2001 the European Commission (the European Union's administrative body) issued its "White Paper on a Future Chemicals Strategy," outlining the Commission's intentions for a fundamentally new integrated chemicals policy. The overarching goals of the policy 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 White Paper emphasizes both increased testing of all chemicals and management of particular high hazard chemicals. It aims to bridge the knowledge and management gap between new (usually more thoroughly tested and managed) and existing chemicals by eliminating this distinction. Specific objectives include:

- Making industry responsible for generating knowledge on chemicals, evaluating risk, and maintaining safety—a duty of care;
- Extending responsibility for testing and management along the entire manufacturing chain;
- Substitution of substances of very high concern and innovation in safer chemicals; and
- Minimization of animal testing. The European Union is currently working on alternative chemical toxicology testing methods through its European Centre for the Validation of Alternative Methods.

The centerpiece of the White Paper and subsequent draft legislation is the establishment of a new integrated chemicals management scheme for the European Union called the REACH (Registration, Evaluation and Authorization of Chemicals) process. The REACH process contains the following elements:

REGISTRATION

Within eleven years after REACH is enacted, all chemicals in commerce marketed over one metric ton per year (some 30,000 substances) must be registered or risk being prohibited from the market. The highest production volume chemicals will have shorter deadlines. Manufacturers and importers of chemicals will be required to submit a registration dossier including: data on identity and properties of substances; intended uses and exposures; production quantity; hazard classification; safety data sheet; preliminary risk assessment for intended uses and disposal (with Commission guidance); and proposed risk management measures. Downstream users of chemicals also will be required to provide information under the scheme, though there is an incentive for them to place testing and safety responsibility on chemical manufacturers. The registration will require basic ecological and human toxicity testing, which will be tiered based on production volume, with substances produced in the range of 1 to 10 tons

The REACH program bridges the knowledge and management gap between new and existing substances by including basic, but flexible, testing requirements for all chemicals in commerce and instituting preventive action for those chemicals of highest concern.

While the costs of implementation of REACH will be great, these are primarily industry testing costs and most analyses have not considered the health and ecosystem benefits associated with REACH or its potential to stimulate innovation in safer substances.

requiring only testing data and others requiring more extensive tests. Registration exemptions will be allowed for most chemical intermediates and polymers and for research and development. The testing requirements are to be flexible in nature, designed to obtain key hazard and exposure information, allowing companies to enter into consortia to prepare data and create supply chain linkages.

EVALUATION

Chemicals produced over 100 tons per year (about 5,000 substances) and those of particular concern will undergo an evaluation process conducted by the Member States. Evaluation is designed to avoid duplicative testing while screening risks. The evaluation can include the development of substance-tailored testing programs. Evaluation can result in proposals for accelerated risk management measures, including restrictions and bans of substances.

AUTHORIZATION

Chemicals of greatest concern based on their inherent hazardous characteristics will have to undergo an authorization process to continue

their use, much like regulations on pharmaceuticals. Authorization will be made on a case-by-case basis considering socio-economic impact, necessity, substance risk for that use, and economic and technical feasibility of alternatives. Authorization will apply to approximately 1,400 chemicals that are known or highly suspected carcinogens, reproductive toxicants or mutagens, as well as persistent organic pollutants (POPs). The list also includes substances that are persistent, bioaccumulative and toxic (PBTs), very persistent and bioaccumulative substances regardless of toxicity (VPVBs), and certain other substances giving rise to similar levels of concern (such as endocrine disrupting substances and sensitizers).

While much of the work of implementing the REACH program will occur in the European Member States, the REACH program will establish a new agency for data collection, program administration, and technical support.

The European Union is the world's largest chemical producer, representing about 28 percent of worldwide chemical output. The industry is Europe's third largest, employing approximately 1.7 million people and comprising about 36,000 small and medium sized enterprises. There have been several economic impact analyses of the REACH proposal which have varied widely in estimating the impacts of the REACH program. An analysis com-

The Generational Goal

Underscoring long-term chemicals management

The REACH program as well as several member state policies and international treaties are guided by the concept of the Generational Goal—which implies the elimination of hazardous chemicals within one generation. This concept was first established in the 1995 Esbjerg Declaration of the Fourth International Conference on the Protection of the North Sea. In some policies the Generational Goal is a legally binding commitment, while in others it serves as a political driver and accountability measure. More than just a statement of policy, European governments are strongly committed to implementing steps to achieve this goal. It was integrated into the declaration from the 2002 World Summit on Sustainable Development. The Esbjerg Declaration defines the Generational Goal. "The prevention of pollution of the North Sea by continuously reducing discharges, emissions and losses of hazardous substances thereby moving towards the target of their cessation within one generation (25 years) with the ultimate aim of concentrations in the environment near background values for naturally occurring substances and close to zero concentrations of man-made synthetic substances."

missioned by the European Commission estimates that implementation of REACH would cost in the range of 1.4 to 7 billion Euros, 85 percent of which would be costs associated with testing and would fall on manufacturers. Analyses to date have generally not fully considered the health, ecosystem, and chemicals management benefits associated with REACH or its potential to stimulate innovation in safer substances through its authorization and testing requirements. However, one analysis indicates that just the occupational health and safety benefits of REACH alone will surpass the costs of implementation. Another found that REACH will generate overall net benefits. These benefits would be achieved, in part, by allowing more rapid interventions to prevent exposures and providing information and regulatory signals to stimulate voluntary actions.

The fundamental restructuring of chemicals regulation in the European Union is a monumental task and many detailed questions need to be addressed. The Commission established multi-stakeholder working groups in 2001 to provide technical advice on the program's implementation. Some difficult issues that the Commission has considered include:

- Establishment of a workable system that is gradually implemented and does not overload regulatory authorities or adversely impact industry.
- Scope of the REACH program, in terms of numbers and types of chemicals covered, and

the extent of the registration and authorization processes.

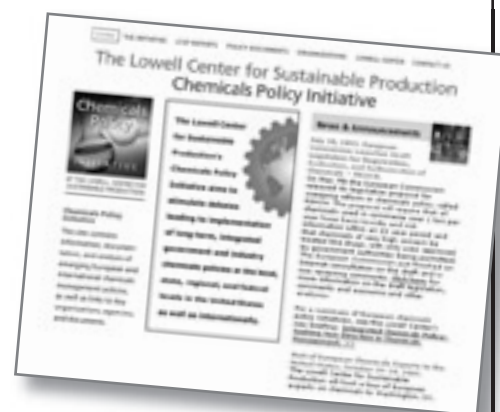
- Application of the REACH program to downstream users of chemicals, as well as to products, including imported ones.
- Ensuring adequate supply chain and public access to information while protecting legitimate confidential business information.
- Integration of the REACH program with other regulatory programs addressing chemicals such as pollution prevention and control, product policy, and occupational health.
- Establishment of a new agency to coordinate the REACH program, including distribution of responsibilities with Member States.

The draft REACH legislation was submitted for stakeholder comment in May 2003 and a final draft will be completed by fall 2003 and then debated by the European Parliament and Council of Ministers (the European legislative bodies). It is expected that legislation will be finalized by 2006, with its entrance in force soon thereafter. Timing will depend in part on the positions of the new accession countries from Central Europe, which will join the European Union in 2004.

The REACH program represents a fundamental change in chemicals management in Europe and there have been many difficult questions to consider to ensure its effective implementation. Draft legislation is expected in 2003 with enactment by 2006.

Visit www.chemicalspolicy.org

More information on European and international chemicals policies can be obtained on the Lowell Center's Chemicals Policy Initiative Website (www.chemicalspolicy.org). The site contains Lowell Center reports providing an in-depth analysis of the drivers, scope, implementation and impacts of emerging European Union and Member State chemicals management policies as well as additional reports on initiatives at the state and federal levels in the United States. The site also contains additional analyses, government documents, and stakeholder positions and a comprehensive list of links to organizations and programs on chemicals policy.



Global Approaches to Chemicals Management



International chemicals policies, such as the Oslo and Paris Convention and the Stockholm Convention on Persistent Organic Pollutants, establish detailed processes for reducing and replacing problem chemicals that persist, bioaccumulate, and have global reach.

The new European chemicals policy proposals have been shaped, to a great degree, by obligations resulting from regional and global international treaties, agreements, and programs. The European Union has used these international initiatives to support and strengthen their new policies; to harmonize international standards upwards; to “pull along” less advanced or more reactive European countries with less proactive policies; and to protect the European Union from potential trade-related disputes as a result of chemicals restrictions.

Some of the most important international treaties and programs influencing current European approaches to chemicals management include:

- *The Oslo and Paris (OSPAR) Convention for Protection of the Marine Environment of the North-East Atlantic.* The OSPAR Convention, adopted in 1992, builds on two previous conventions addressing marine pollution in the Northeast Atlantic. This convention of Northeast Atlantic nations, including the European Commission, can adopt binding decisions to protect the marine environment by requiring the prevention of pollution from land-based and off-shore sources. A 1998 OSPAR Strategy on Hazardous Substances establishes a process for eliminating hazardous inputs in the region within one generation through: development of tools for assessing risks of potential hazardous substances in the marine environment; identification and prioritization of chemicals of concern; and development of action plans on priority substances.

- *The 2001 Stockholm Convention on Persistent Organic Pollutants.* The Stockholm Convention establishes a legally binding means to address threats to health and the environment caused by persistent organic pollutants (POPs). It establishes an international production phaseout of 12 substances including already restricted pesticides, polychlorinated biphenyls, and dioxins and furans. It also provides for financial and technical assistance so that developing countries can inventory and destroy existing stocks of POPs; international

research and monitoring of POPs; and a “precautionary” process to add new POPs to the Convention’s list, based on evidence of risk and long-range transport, even where full information is not available.

The United Nations has undertaken several other initiatives to reduce risks from the global circulation of chemicals. The *Global Mercury Assessment* aims to characterize and reduce risks to health from exposure to mercury. 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 substance, 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)* is a UN-sponsored effort of 120 countries as well as non-governmental, industry, and labor organizations. It provides policy guidance, identifies priorities, produces information, develops strategies and makes recommendations for collective action on chemicals classification and labeling, pollution prevention, and hazard reduction.

The United Nations is now trying to unify its disparate efforts under the rubric of a newly established Strategic Approach to International Chemicals Management.

US Approaches to Integrated Chemicals Management

Integrated chemicals policy discussions are not new in the United States. Many of the early federal and state environmental protection statutes contained bold and far-reaching chemicals management goals and policies. In particular, the federal Toxic Substances Control Act (TSCA) specified an effective program for addressing the hazards of new chemicals entering the market after 1980. Through a multi-disciplinary, lifecycle review process, the TSCA new chemicals program focuses attention on deterring the production and marketing of potentially harmful substances and encouraging development of greener chemicals and production processes.



Extensive multi-stakeholder discussions on chemicals policy occurred in the Great Lakes region during the 1980s and early 1990s. The 1978 renewal of the Great Lakes Water Quality Agreement called for the parties to “restore and maintain the chemical, physical, and biological integrity of the water of the Great Lakes Ecosystem” through programs to “virtually eliminate the input of persistent toxic substances in order to protect human health and the productivity of living aquatic resources.” In its 1992 and 1994 Biennial Reports, the U.S.-Canada International Joint Commission, which provides expert advice for 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 U.S., and Great Lakes state governments. This regional chemicals policy vision has become stalled by a lack of political will.

The federal Emergency Planning and Community Right-to-Know Act, combined with passage of the Pollution Prevention Act led to increased federal focus on source reduction as a priority for chemicals and materials management. Through its Office of Pollution Prevention and Toxics, the U.S. Environmental Protection Agency (EPA) has supported a number of voluntary outreach, education and demonstration programs to encourage industry

to reduce chemicals use, develop cleaner, safer chemicals and chemical syntheses and design cleaner products. These include various sector-based initiatives, such as the Common Sense Initiative and the Cleaner Technology Substitutes Analysis Program, as well as a Green Chemistry Program and the Design for Environment Program. The EPA’s Persistent Bioaccumulative Toxics Program (PBTs), focuses on reduction of PBTs in waste streams. Through its High Production Volume Challenge and its Voluntary Children’s Testing Program, EPA also is encouraging industry to develop better data on chemical risks. While useful tools for chemicals management, these programs have not led to extensive attention to chemicals in products or an integrated chemicals management approach.

Given the slow pace of federal government regulations on hazardous chemicals, several states have acted on their own. Massachusetts and New Jersey have highly successful mandatory pollution prevention planning regulations. Other states have enacted pollution prevention laws focused on education, outreach demonstration projects, and state-sponsored technical assistance.

The federal Emergency Planning and Community Right-to-Know Act, as well as the Pollution Prevention Act, have led to an increased federal focus on source reduction and information on toxic substances as priorities for chemicals and materials management.

One of the most successful state laws addressing toxic substances in products is the 1986 California Safe Drinking Water and Toxic Enforcement Act (or “Proposition 65”), which prohibits businesses from discharging chemicals with carcinogenic or reproductive toxicity effects into sources of drinking water. Under the law, the state government is required to maintain a list of chemicals covered by the act. 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 label products. In summer 2003, California passed a bill that prohibits two polybrominated diphenyl ethers.

Since the late 1990s, 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 has designated nine PBTs for reduction, and included 13 more in the “PBT Working List” of chemicals on which to focus in future action plans. The state Department of Ecology is implementing the program through monitoring, public education and outreach, research, and procurement.

In 1999, the governor of Oregon issued an executive order directing state officials to achieve zero discharge of persistent chemicals by 2020. Several states, including New Hampshire, Vermont, Maine, Rhode Island, Oregon and Connecticut, have passed legislation to phase out the use of mercury in various consumer products. Other states and localities have established procurement policies that prohibit the use of certain chemicals and encourage the purchasing of others in government contracts.

A U.S. Success Story in Chemicals Management

The Massachusetts Toxics Use Reduction (TUR) Program

Passed in 1989, the Massachusetts Toxics Use Reduction Act encourages firms to identify ways to reduce their reliance on listed toxic substances rather than calculate acceptable emissions levels. Manufacturing firms using more than 10,000 pounds per year of toxic substances are required to annually calculate their toxic materials use and waste generation. They must then develop plans and thoroughly examine options to reduce their waste and use of toxic substances and measure progress. Summaries of these plans and materials accounting data are publicly available. Fees on toxic chemicals use funds the regulatory program as well as voluntary technical assistance to industry, and a research and training program that assists firms and communities in seeking safer chemicals, processes, and products.

The success of the Act makes it an impressive model. Over a ten-year period, toxic chemical emissions in Massachusetts have been reduced by more than 80 percent; toxic waste, almost 60 percent; and toxics chemical use, almost 40 percent, indexed for changes in manufacturing activity. Massachusetts firms have saved more than \$15 million in the process, excluding the unquantifiable benefits for health and the environment (see www.turi.org). The state is now working on implementation of a voluntary significant reductions program for five high hazard chemicals—mercury, lead, trichloroethylene, arsenic, dioxins and furans. The toxics use reduction program, however, only applies to manufacturing firms in Massachusetts and has thus not included chemicals in products produced outside of the state. A newly proposed bill in Massachusetts, the Act for a Healthy Massachusetts, attempts to address this gap by calling for the substitution of ten problematic chemicals in production systems and products when feasible safer alternatives are available. It contains provisions for addition of new substances and for research and development and technical assistance on safer substitutes.

S U M M A R Y

Nordic countries such as Denmark and Sweden have actively promoted integrated chemicals policies over the past decade to address contamination of critical waterways. They have successfully used a variety of voluntary and mandatory policy tools—such as education, procurement, lists of chemicals of concern, ecolabeling, research and development on safer substitutes, and chemical phaseout requirements—to encourage companies using chemicals to reduce their reliance on harmful substances and to develop safer alternatives.

While previously isolated to particular countries, innovative and exciting European-wide policies to promote sustainable chemicals management are now moving forward. These policies have been spurred by several factors: (1) increasing recognition of the limitations of current chemicals policies and a lack of confidence in the chemical industry; (2) concerns about health and ecosystem impacts of chemical exposures, particularly from everyday products; and (3) long-term political commitments to environmental quality improvement and reduction of hazardous chemicals—the so-called Generational Goal. A sweeping change in chemicals management policies in Europe is inevitable.

Through a slow, thoughtful education process and public debate among various stakeholders (industry, government, advocates, and academics), the European Union and Member States have been able to build sufficient momentum for fundamentally restructuring chemicals management policies and to create an integrated chemicals policy embodied in the Registration, Evaluation and Authorization of Chemicals (REACH) proposal. This new policy will require basic data on all chemicals in commerce, information on risks throughout chemical lifecycles, rapid evaluation of chemical risks, and substitution of those substances of highest concern. The new European chemicals policy—representing the most ambi-

tious piece of chemicals regulation in the past 25 years—is expected to be in force by 2006 and will set the global standard for chemicals management.

The REACH proposal and discussions leading up to it go far beyond any comparable U.S. initiative, which has resulted in a reluctance of some government and industry officials to support its adoption in this country. Yet, new European policy will affect manufacturers in the United States and globally. Some U.S. manufacturers, such as those in the electronics and auto industries, are already working to implement aspects of the REACH program and identify substitutes for those chemicals that may face restrictions. It is in the best interests of forward-looking governments and companies to be at the forefront of the global momentum to reduce the impacts of toxic substances on health and ecosystems by developing policies to gather data on chemical risks throughout their lifecycle as well as to identify and substitute less harmful chemicals.

Further information on chemicals policies can be obtained at the following websites:

- Lowell Center Chemicals Policy Initiative: www.chemicalspolicy.org
- European Commission: europa.eu.int/comm/environment/chemicals/ or europa.eu.int/comm/enterprise/chemicals/index.htm
- Swedish Chemicals Inspectorate: www.kemi.se/default_eng.htm
- Danish Environmental Protection Agency: www.mst.dk/homepage/
- European Environment Bureau: www.eeb.org
- European Chemical Manufacturers Trade Association—CEFIC: www.chemicalspolicyreview.org
- United Nations Chemicals Program: www.chem.unep.ch/irptc/default.htm
- U.S. Environmental Protection Agency: www.epa.gov/oppt

About the Lowell Center for Sustainable Production

The Lowell Center for Sustainable Production (The Lowell Center) at the University of Massachusetts Lowell is internationally recognized as a leading academic institute in innovative research, model policy development, and training programs to support sustainable production and consumption. Through close collaboration with environmental organizations, government agencies, businesses, and trade unions, the Center studies, develops, and promotes environmentally sound systems of production, healthy work environments, and economically viable work organizations. The Lowell Center is an international leader in the promotion of cleaner production, product stewardship, sustainable consumption, and the precautionary principle.

The Lowell Center's Chemicals Policy Initiative aims to inform and stimulate discussions leading to implementation of long term integrated government and industry chemicals management policies. Such chemicals policies must be viewed in a holistic and integrated context—to protect worker, community, and consumer health while stimulating development of safer and cleaner production systems, materials, and products. The Initiative's objectives are to:

1. Develop a vision for sustainable, integrated chemicals policy;
2. Inform and educate a broad range of U.S. and international stakeholders on European, U.S. and international chemicals policy initiatives;
3. Develop linkages between experts in Europe and the United States to share experiences and strategies for integrated chemicals policy;
4. Support establishment of government and industry integrated chemicals policy initiatives at the state and federal levels in the United States and abroad.

For more information about the Lowell Center for Sustainable Production's Chemicals Policy Initiative and the Lowell Center's other initiatives, please visit the Center's website at www.chemicalspolicy.org or www.sustainableproduction.org.



Lowell Center for Sustainable Production

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