Reshaping Chemicals Policy on Two Sides of the Atlantic:

Ecosystem Impacts of Current Approaches and the Promise of Improved Sustainability through International Collaboration

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I. Introduction

Despite the enormous scale of global chemical production, decades-old U.S. chemicals regulations have proven insufficient as health and environmental protections. Their effectiveness is critical to health and ecosystems: each day, 74 billion pounds of chemical substances are produced or imported in the United States (U.S.)[1], a figure that is projected to double in two decades (Figure 1).[2] [3] All of these substances – or their degradation products - ultimately enter the earth's finite ecosystems. Many ecosystems that have been assumed to possess unlimited assimilative capacity are now suffering from exposure to both legacy and "emerging" chemical contaminants. [4] [5] These effects can move beyond individual species to impact the ecosystem as a whole, illustrating the links between the chemical enterprise and global environmental problems.[6] [7]

As the environmental health sciences evolve, U.S. chemicals policy has lagged. Based on outdated scientific evidence and insufficient public health protections, these policies likewise fail to reflect global regulatory changes and shifting societal priorities which—from climate change to chemical hazards—are increasingly valuing precautionary decision-making. [8] The primary U.S. statute governing chemicals, the *Toxic Substances Control Act* (TSCA), has proved an ineffective vehicle for (1) assessing the hazards of the great majority of chemicals; (2) controlling those of greatest concern; or (3) motivating investment in the science, technology and commercial applications of cleaner chemical technologies, known collectively as green chemistry.[9] These weaknesses have produced three chemicals policy "gaps" in the U.S.: the Data Gap, the Safety Gap, and the Technology Gap (Figure 2).[10]

By contrast, in the last five years the European Union (EU) has instituted sweeping policies governing chemicals and products. Most notable is the *Registration, Evaluation, Authorisation and Restriction of Chemicals* (REACH) regulation. REACH represents a fundamental paradigm shift in four key areas: (1) legal implementation of the precautionary principle, (2) shifting the burden of proof of safety to producers for chemicals, (3) requiring the use

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[1] U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. *2006 Inventory Update Reporting: Data Summary*. U.S. EPA, Office of Pollution Prevention and Toxics, Publication 740S08001, 2006. http://www.epa.gov/oppt/iur/pubs/2006_data_summary.pdf (Accessed March, 2009).

[2] Organization for Economic Cooperation and Development (OECD), *Environmental Outlook for the Chemicals Industry* (OECD, 2001), 34-36. http://www.oecd.org/dataoecd/7/45/2375538.pdf (Accessed March, 2009).

[3] American Chemistry Council, *Guide to the Business of Chemistry* (American Chemistry Council, Arlington, Virginia, 2003), 78.

[4] B. M. Braune et al., "Persistent organic pollutants and mercury in marine biota of the Canadian Arctic: An overview of spatial and temporal trends," *Sci. Total Environ.* 351–352 (2005): 4– 56

[5] M. Scheffer, S. Carpenter, J. A. Foley, C. Folkes, B. Walker, "Catastrophic shifts in ecosystems," *Nature* 413 (2001): 591-596.

[6] F. Stuart Chapin III et al., "Biotic Control over the functioning of Ecosystems," *Science* 277 (1997): 500-504.

[7] P. M. Vitousek, H. A. Mooney, J. Lubchenco, J. M. Melillo, "Human Domination of Earth's Ecosystems," *Science* 277 (2008): 494-499.

[8] D. Gee, "Late lessons from early warnings: toward realism and precaution with endocrine-disrupting substances," *Environ Health Perspectives* 114 (2006): 152–160.

[9] National Pollution Prevention and Toxics Advisory Committee, Broader Issues Work Group, *How can EPA more efficiently identify potential risks and facilitate risk reduction decision for non-HPV existing chemicals?* National Pollution Prevention and Toxics Advisory Committee October 2005, http://www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf (Accessed March, 2009).

[10] M. Wilson, M. Schwarzman, "Toward a New U.S. Chemicals Policy: Rebuilding the Foundation to Advance New Science, Green Chemistry and Environmental Health," *Environ Health Perspect*. 117 no. 6 (2009), http://www.ehponline.org/members/2009/0800404/0800404.pdf.

of safer substitutes for certain substances considered of very high concern, and (4) improving communication between chemical producers and downstream users. These changes, combined with an influx of chemical-related information will begin to address the lack of transparency and accountability in the chemicals market. As a result, REACH is expected to shift global markets in favor of cleaner technologies, including green chemistry.

The widening gulf between U.S. and European environmental regulation presents both an opportunity and an imperative for the U.S. to retool its approach to chemicals policy. Robust economic ties between California and the EU, including Europe's significance as an export market for California, make Europe's recent slate of chemicals regulations particularly significant for the state. Within the U.S., California has historically set the benchmark in environmental regulation. True to form, in September 2008, the state Legislature enacted two bills that take initial steps toward a more comprehensive chemicals policy, providing an opening for a two-way exchange between California and the EU.

II. Biodiversity, Ecosystem Services and the Chemical Enterprise

Many ecosystems—and the diversity of organisms that support them—are in decline worldwide. While models vary, it is estimated that in the last century, human activities have caused between 100 and 1,000 times more species extinctions than would have been expected from natural causes, and the rate of loss is projected to increase 10-fold by 2050.[11] Chronic effects of background-level exposures to synthetic chemicals and pollutants—in combination with other stressors, such as climate change and habitat loss—can contribute to species' reproductive failure, disruption of food webs, population declines and ultimately loss of both species and genetic variety.[12] [13]

A region's biodiversity determines many aspects of the productivity and sustainability of ecosystems.[14] Ecosystem integrity is fundamental to societal sustainability, not only through the inherent value of nature but through the provision of ecosystem services, a term that describes the value to humans of nature's "services," such as crop pollination, soil generation, pest control, waste detoxification, reduction of air pollution and water contamination, the provision of food, fiber and medicine, and the mitigation of the effects of floods, droughts and temperature

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[11] Millennium Ecosystem Assessment, *Ecosystems and Human Well-being: Biodiversity Synthesis*. Washington D.C.: World Resource Institute 2005. http://www.millenniumassessment.org/documents/document.354.aspx.pdf (Accessed March 2009).

[12] W. Bickham, S. Sandhu, P. Hebert, L. Chikhi, R. Athwal, "Effects of chemical contaminants on genetic diversity in natural populations: implications for biomonitoring and ecotoxicology," *Mutat. Res.* 463 (2000): 33-51.

[13] A. Boxall et al., "Impacts of Climate Change on Indirect Human Exposure to Pathogens and Chemicals from Agriculture," *Environ Health Persp.* 117 no. 4 (2009), http://www.ehponline.org/docs/2008/0800084/abstract.html (Accessed March, 2009).

[14] Secretariat of the Convention on Biological Diversity, *Global Biodiversity Outlook 2.* Montreal, QC Canada: Convention on Biological Diversity 2006. http://www.cbd.int/gbo2/ (Accessed March, 2009).

extremes.[15] Because biodiversity contributes to human well-being in the form of ecosystem services, many of the advancements made possible by the chemical enterprise have come with a substantial societal cost. [16] [17]

The Role of the Chemical Enterprise

Chemical substances are enormously useful to society, yet they can also be toxic to humans and ecosystems. Despite this fact, there is a striking lack of information about the health and environmental effects of most synthetic chemicals. Hundreds of industrial chemicals and pollutants have been detected in people, and in aquatic and terrestrial ecosystems around the world. [18] [19]

Two recent U.S. studies have highlighted the contribution of chemical contamination to threats to biodiversity in the form of habitat loss and health effects in indicator species. An assessment of western U.S. national parks found widespread chemical contamination of these ecosystems with persistent, bioaccumulative organic compounds—many of which are known to damage vegetation and wildlife—as well as health effects associated with chemical exposure in several species.[20] Similarly, a study of bird eggs from both populous and remote areas in Maine found over 100 chemical contaminants, known to cause detrimental health effects in animals.[21] In both studies, contaminants originated from manufacturing processes as well as commercial products traceable to both regional and remote sources. Such studies—as well as others highlighting the concentration of contaminants in the arctic—demonstrate that environmental contamination is a truly global issue; like greenhouse gases, synthetic chemicals do not respect national boundaries, nor are their effects confined to the areas of greatest production and use. As such, they require global solutions.

Role of Precaution

Expanding global pollution with persistent, bioaccumulative chemicals raises the specter of unwittingly passing harm on to future generations. Chemicals policies should therefore aim to reduce the potential for harm, even

[15] G. C. Daily, et al., "The Value of Nature and the Nature of Value," *Science* 289 (2000): 395-396.
[16] P. J. Landrigan, C. B. Schechter, J. M. Lipton, M .C. Fahs, J. Schwartz, "Environmental Pollutants and Disease in American Children: Estimates of morbidity, mortality and costs for lead poisoning, asthma, cancer, and developmental disabilities," *Environ Health Persp*. 110 (2002): 721-728.
[17] T. Muir, M. Zegarac, "Societal Costs of Exposure to Toxic Substances: Economic and Health Costs of Four Case Studies That Are Candidates for Environmental Causation," *Environ Health Persp*. 109 (2001): 885–903 .
[18] U.S. Centers for Disease Control and Prevention, *Third National Report on Human Exposure to Environmental Chemicals.* Atlanta GA: CDC 2005. http://www.cdc.gov/exposurereport/report.htm (Accessed March, 2009).
[19] B. M. Braune, et al., "Persistent organic pollutants and mercury in marine biota of the Canadian Arctic: An overview of spatial and temporal trends," *Sci. Total Environ.* 351–352 (2005): 4– 56.
[20] D. H. Landers et al., *The Fate, Transport, and Ecological Impacts of Airborne Contaminants in Western National Parks.* EPA/600/R-07/138. Corvallis, Oregon: U.S. Environmental Protection Agency Publication, Office of Research and Development, NHEERL, Western Ecology Division, 2008.
[21] Biodiversity Research Institute (Gorham, Maine, 2008), Biodiversity Research Institute Website, http://www.briloon.org/index.php (Accessed March, 2009).

where definitive evidence of cause and effect relationships is not yet established, as described by the precautionary principle.[22]

The theoretical basis for regulatory responses to scientific evidence determines much about how health-protective the regulations are. Like other environmental regulations, chemicals policies use differing standards of evidence, ranging from the most precautionary "scientific suspicion of risk", to the most stringent "clear evidence of cause-and-effect" (See Figure 3).[23] Scientific evidence of the health and environmental effects of chemicals likewise exists along a continuum; evidence is generally not simply "sound" or "unsound," as some industry representatives have argued.[24] As a result, regulatory decisions must be made despite uncertainty. As a result, decision-making tools need to be both efficient, recognizing that "perfect information" is unobtainable, and scientifically robust.

In a 1994 consensus resolution, the American Public Health Association argued that the lack of "perfect information" should not be used as a reason for delaying policy decision-making.[25] This assertion recognized the difficulty establishing proof of cause-and-effect relationships because of nonspecific health outcomes, long latency periods, disease endpoints detectable only by resource-intensive studies, and complex interactions of variables that contribute to disease. On this basis, the resolution espoused a precautionary approach: where there are threats of serious or irreversible damage to health or the environment, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Precautionary decision-making is a response to the contingent nature of scientific knowledge and the complexity of natural systems. It aims to reduce the likelihood, extent and severity of the surprises that can arise from scientific ignorance. This is distinct from prevention, which seeks to reduce risks only from well-established hazards.[26] While TSCA requires EPA to meet the highest evidentiary standard, European chemicals policies have codified a precautionary approach by switching from a "presumption of innocence" to a requirement that producers provide information as a condition of use and, further, prove the safety and necessity of chemicals, particularly for chemicals of high concern.

A Green Chemistry Alternative

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[22] C. Raffensperger, J. Tickner, *Protecting Public Health and the Environment: Implementing the Precautionary Principle* (Washington, DC: Island Press, 1999).

[23] European Environment Agency, *Late Lessons from Early Warnings: The Precautionary Principle, 1896-2000.* Luxemberg: European Environment Agency, Office for Official Publications of the European Communities, 2001. http://www.eea.europa.eu/publications/environmental_issue_report_2001_22/Issue_Report_No_22.pdf (Accessed March, 2009).

[24] D. Michaels, "Doubt is their product: Industry groups are fighting government regulation by fomenting scientific uncertainty," *Scientific American* (June, 2005): 96-101.

[25] American Public Health Association, "Policy Statements Adopted by the Governing Council," *Journal of the American Public Health Association* 91 (2001): 20-21.

[26] D. Gee, "Late lessons" 2006

Green chemistry describes the development of novel chemicals and manufacturing processes to improve their inherent safety and prevent—rather than reduce or remediate—the impacts of chemical exposures and environmental contamination. In essence, green chemistry aims to "design out" health and environmental hazards, while reducing the consumption of energy, water and non-renewable feed-stocks, and generating fewer hazardous byproducts and waste.[27] Realization of these goals required policies to identify, prioritize and take action on chemicals of concern, as well as to increase the value and speed the development of safer technologies.

IV. Gaps in U.S. Chemicals Policy

The decades-old U.S. chemicals regulation known as the *Toxic Substances Control Act* of 1976 (TSCA), has proven ineffective in protecting human health or the environment.[28] TSCA has prevented the basic process of identifying and prioritizing chemicals, has deprived the U.S. Environmental Protection Agency (EPA) the market and regulatory tools sufficient to control the chemicals of greatest concern, and has failed to support the development of safer substances, based on the principles of green chemistry. As a result, the U.S. chemicals market undervalues the safety of chemicals relative to their function, price, and performance, and hazardous chemicals remain competitive and in widespread use. This is attributable to what we characterize as three overarching policy "gaps" in TSCA:[29]

Data Gap: Producers are not required to investigate and disclose sufficient information on the hazard traits of chemicals.

Safety Gap: Government does not have the information it needs to identify potential chemical hazards or risks, nor effective legal tools to mitigate them;

Technology Gap: Following market signals, industry and government have invested only marginally in green chemistry research and education.

The Data Gap

With few exceptions, TSCA does not require producers either to investigate or to disclose information about chemical hazard traits. As a result, most of the 83,000 industrial chemicals in the U.S. inventory lack information on their health or environmental effects.[30] These include 62,000 chemicals that were "grandfathered" in without further review because they were already in use when TSCA was passed in 1976. Ninety-nine percent (by volume) of the highest production volume chemicals currently sold consist of these substances.[31] In addition to the lack of data on pre-1976 chemicals, a U.S. EPA audit revealed that 85% of new chemical notices submitted to EPA on

[27] P. Anastas, J. Warner, *Green Chemistry: Theory and Practice* (New York: Oxford University Press, 1998).
[28] United States Government Accountability Office (U.S. GAO), *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage its Chemicals Review Program.* GAO-05-458. Washington, D.C.: U.S. Government Printing Office, 2005, http://www.gao.gov/new.items/d05458.pdf (Accessed March 2009).
[29] Wilson and Schwarzman, "Toward a New U.S. Chemicals Policy" 2009.
[30] United States Environmental Protection Agency (U.S. EPA), Office of Pollution Prevention and Toxics. *Programs Overview* (Washington DC: Draft Version 2.0, December 2003).
[31] U.S. GAO, *Chemical Regulation* 2005.

chemicals introduced since that time lacked information on their potential health effects, and 67% lack health or environmental data of any kind.[32]

All other federal statutes combined regulate just over 1,000 chemicals and pollutants (Table 1).[33] U.S. EPA has made limited progress in closing the data gap under the voluntary High Production Volume (HPV) Chemical Challenge, which encourages producers to submit only "screening-level" information for about 3,000 chemicals produced or imported at more than one million pounds per year.[34] [35] Also lacking—at both the state and federal level—is information on the identity, volume, location or uses of chemicals in products or manufacturing processes. Likewise, there is virtually no record of their ultimate route of disposal or environmental fate.

The Safety Gap

In addition to insufficient data requirements, TSCA failed to grant the U.S. EPA adequate authority to investigate or regulate chemicals of concern. As a result, the Agency has been virtually unable to control even known hazards: since the passage of TSCA, EPA has issued formal rules to regulate only five chemicals (or chemical classes) of the 83,000 substances in the TSCA inventory.[36] By default, EPA has resorted to voluntary measures to encourage industry submission of data, measures that have been largely ineffectual.[37]

TSCA requires EPA to prove that a chemical or product causes unreasonable harm to human health or the environment *before* the Agency can either request additional health or environmental data from industry or take protective measures. This effectively places EPA in a "logical paralysis:" in order to establish proof of a public health risk, agencies need health and exposure information that chemical producers are under no legal obligation to provide; to require this information, EPA must first establish proof of a public health risk. In the absence of sufficient information, and without an effective legal framework, hazardous chemicals can enter the market and are competitive relative to potentially safer substances.

The Technology Gap

Transitioning from concept to commercial application of cleaner technologies, such as green chemistry, often requires that a company undertake costly research, capital investments and the risks of being a leader in an emerging field. The market and regulatory weaknesses caused by the data gap and safety gap, together with

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[32] U.S. EPA. *Programs Overview* 2003.
[33] J. Dernbach, "The unfocused regulation of toxic and hazardous pollutants," *The Harvard Law Review* 21 (1997): 1-57.
[34] United States Environmental Protection Agency, "High Production Volume (HPV) Challenge," Office of Pollution Prevention and Toxics, http://www.epa.gov/chemrtk/ (Accessed March 2009).

[36] United States General Accounting Office, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*. GAO/IRCED-94103. Washington, DC: U.S. Government Accountability Office, 1994, http://archive.gao.gov/t2pbat2/152799.pdf (Accessed March, 2009).
[37] R. Denison, *Not that Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals*. Washington DC: Environmental Defense, Pollution Probe April 2007, http://www.environmentaldefense.org/article.cfm?contentid=6147 (Accessed March 2009).

institutional inertia and minimal research investment, all make companies reluctant to take on these risks. This is producing a green chemistry technology gap that could place U.S. producers at a disadvantage in this emerging global sector, while perpetuating the problems resulting from the manufacture, use, and disposal of hazardous substances.

The Data, Safety and Technology Gaps engendered by TSCA have produced conditions in the U.S. chemicals market in which businesses, consumers, workers and government agencies lack the information to identify and mitigate risks posed by hazardous chemicals. As a result, the public bears the human and economic burden of health and environmental damage caused by synthetic chemicals.

California vs. the United States

California has historically departed from the U.S. federal approach to environmental policy, responding to complex problems with regulatory reforms that link economic development with environmental protection. Energy-saving policies initiated in the 1970s, for example, altered the course of California's electricity consumption: the state now uses just over 50% of the electricity per capita compared to the nation as a whole, markedly reducing greenhouse gas emissions and saving a total of $56 billion for individuals and businesses through 2003.[38] More recently, California's success in reducing vehicle emissions has improved the state's air quality and has stimulated innovation in lower-emission technologies nationwide.[39] With the issue of chemicals policy reform on the table for both the Obama Administration and the current Congress,[40] [41] California thus has an unprecedented opportunity to affect federal policy by restructuring state chemicals regulation.

The state has recently taken important steps toward leadership in chemicals policy. Seeking to drive investment in green chemistry and a shift toward a safer universe of chemicals, the California Environmental Protection Agency (Cal/EPA) launched a Green Chemistry Initiative in 2007.[42] In September, 2008, the California Legislature passed two laws (AB 1879, Feuer and SB 509, Simitian) aimed at increasing transparency and accountability in the chemicals market. Scientists and environmental advocates are now calling on the state to further shift the regulatory structure from one governed by a "presumption of innocence" to a more precautionary approach. This follows the lead of the EU and opens new opportunities for collaboration.

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[38] California Energy Commission, *2007 Integrated Energy Policy Report*. CEC-100-2007-008-CTF. November 2007, 2-7. http://www.energy.ca.gov/2007publications/CEC-100-2007-008/CEC-100-2007-008-CTF.PDF (Accessed March 2009).

[39] National Academy of Sciences, National Research Council, Division on Earth and Life Studies, Standards Board on Environmental Studies and Toxicology, Committee on State Practices in Setting Mobile Source Emissions, *State and Federal Standards for Mobile-Source Emissions* (Washington DC: The National Academies Press, 2006).

[40] U.S. Congress. Senate. *S. 3040 Kids Safe Chemicals Act of 2008.* 110th Cong. 2007-2008, http://www.govtrack.us/congress/bill.xpd?bill=s110-3040 (Accessed May, 2009).

[41] Government Accountability Office, Report to the Congress *High Risk Series: an Update*. GAO 09-271. Washington, DC: US Government Printing Office, January, 2009. http://www.gao.gov/new.items/d09271.pdf (Accessed May, 2009).

[42] California Department of Toxic Substances Control, "California Green Chemistry Innitiative," California.gov website, http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/index.cfm.

V. A more Protective Chemicals policy: European Union

In the late 1990s, the EU identified problems similar to those traced in the U.S. to weak oversight of industrial chemicals. [43] However, Europe has responded with a slate of policies that (1) establish means for managing both new and existing chemicals (REACH), (2) take immediate action on chemicals of high concern in certain applications (RoHS and Cosmetics Directive) and (3) set up a framework for product stewardship and producer responsibility for the full life cycle of electronic and electrical equipment (WEEE). Together, these policies are expected to shift the market to favor investment in green chemistry technologies, with the potential, ultimately, to improve the safety of the substances which comprise the material basis of society. The recent regulations include:

1. The Cosmetics Directive, prohibits the use of 1,000 known or suspected carcinogens, mutagens, or reproductive toxicants in cosmetics (2004)[44]
2. The Waste in Electrical and Electronic Equipment (WEEE) Directive, requires producers to take back products at the end of their useful life (2005)[45]
3. The Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Regulation, prohibits the use of lead, cadmium, mercury, and certain flame-retardants in electronics sold in the EU[46]
4. The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation, requires producers to provide hazard and exposure information for approximately 30,000 chemicals and apply for authorization for continued use of certain substances of Very High Concern, with some requirements for substitution. [47]

The last of these, REACH, is the most comprehensive chemicals management regulation in the world. Its basis in the precautionary principle also makes it the most progressive regulation in protecting human health and the environment from the adverse effects of hazardous chemicals.

Structure of REACH

REACH requires manufacturers to register with the European Chemicals Agency (ECHA) any chemical produced or imported at more than one metric ton per year (“ton per annum,” or tpa). Over the ten year registration phase, this is expected to make basic information available for an estimated 30,000 chemicals. More comprehensive hazard information will be reported for a subset of approximately 12,000 substances, with more extensive data required for chemicals produced in larger volumes. Most of the chemical hazard information submitted to the

[43] European Comission, *White Paper on the Strategy for a Future Chemicals Policy*. COMM 88. Brussels: February 2001, http://ec.europa.eu/off/white/index_en.htm (Accessed March 2009).
[44] Enterprise and Industry Directorate General of the European Commission, *Consolidated Version of Cosmetics Directive 76/768/EEC*. European Commission, November 2007, http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm (Accessed March 2009).
[45] Environment Directorate General of the European Commission, *Waste Electrical and Electronic Equipment.* European Commission, January 2008, http://ec.europa.eu/environment/waste/weee/index_en.htm (Accessed March 2009).
[46] RoHS, “The RoHS regulation, Directive 2002/95/EC: Major regulation's provisions,” RoHS Website, http://www.rohs.eu/english/index.html (Accessed March 2009).
[47] European Parliament. *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).* Official Journal of the European Union, 2006.

European Chemicals Agency (ECHA) will be publicly accessible to residents of the EU, as well as to NGOs and foreign governments.

From the database of registered substances, EU Member States will use hazard and exposure information to identify chemicals for further evaluation. Simultaneously, Member States and ECHA can use the criteria for identifying SVHCs to nominate chemicals for the list of candidate substances for authorization.[48] ECHA is then tasked with recommending to the European Commission priority substances from the candidate list whose uses will have to be individually authorized. ECHA has published an initial Candidate List of chemicals and has selected substances from the Candidate List as priority substances to be included in Annex XIV of REACH. Annex XIV names the substance which will be subject to use-specific authorization, phase-out or substitution requirements.[49] Both, the candidate list and Annex XIV will grow as Member States and ECHA continue to propose chemicals for inclusion on the Candidate List.

Impacts of REACH

The REACH regulation codifies fundamental paradigm shifts in four areas: (1) legally implementing the precautionary principle, (2) shifting the burden of proof of safety to chemical producers, (3) requiring the use of safer substitutes for certain substances considered of very high concern and (4) improving communication between chemical producers and downstream users. Coupled with the directives that require product stewardship (WEEE) and restrict some hazardous substances in particular product categories (RoHS and the Cosmetics Directive), REACH has the potential to place human and environmental safety at the center of purchasing decisions at all levels in the chemical supply chain. This could fundamentally shift global markets in favor of cleaner technologies, including green chemistry.

Several elements of REACH are particularly significant:

(1) Equivalent data requirements for new and existing chemicals: Holding existing (pre-regulation) chemicals to the same information disclosure standards as new (post-regulation) substances effectively removes disincentives to innovation and "levels the playing field".[50]

(2) Supply chain transparency: Substances produced in or imported into the EU at 10 tpa or more are required to produce a Chemical Safety Assessment and provide sufficient information to consumers and commercial users to guide safe use of their products. Additionally, chemical producers will be required to communicate at least the chemical identity of any SVHCs contained in their products, if those SVHCs have been placed on the Candidate List.

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[48] Substances of Very High Concern (SVHC) are carcinogens, mutagens or reproductive toxicants (CMRs); persistent or bioaccumulative toxicants (PBTs); very persistent and very bioaccumulative substances (vPvBs) as well as other substances of "equivalent concern," such as endocrine disruptors.

[49] European Chemicals Agency, "Candidate List of Substances of Very High Concern for Authorisation," European Chemical Agency Website, http://echa.europa.eu/chem_data/candidate_list_table_en.asp.

[50] J. Guth, "Require comprehensive data, 2007.

A parallel requirement dictates that "use" information be communicated back up the supply chain from business end-users to chemical producers, unless end-users themselves undertake the task of demonstrating safety by conducting their own chemical safety assessment. This bi-directional flow of information in the supply chain is expected to facilitate hazard identification and substitution.

(3) Data requirements for chemicals in mixtures and articles: Registration is required for all chemicals included in chemical mixtures and for SVHCs in some articles, based on total volume produced or imported, percentage of the article by weight, anticipated release, and hazard to humans or the environment.

(4) Prioritizing hazardous substances: The process of identifying and prioritizing chemicals of concern is embodied in the Evaluation and Authorization provisions of REACH. While the tasks for ECHA and the Member States are formidable, for the first time, there are clear criteria for identifying particularly hazardous substances, and for those substances, manufacturers will be required either to find substitutes or bear a heavy burden of proof that the chemical is safe or that suitable alternatives are lacking. Anecdotal evidence suggests that publication of the Candidate List, which in itself has limited regulatory consequences, is nevertheless triggering some companies to eliminate known hazardous chemicals from their portfolios in advance of regulation.

Potential Limitations of REACH

In both its scope and its basis in the precautionary principle, REACH is truly a landmark regulation. Decisions made during the implementation phase, however, will determine much about its impact.

(1) Data requirements do not apply to all chemicals in commerce—Chemicals produced or imported in quantities less than 1 tpa per producer will not be subject to registration, the most basic requirement under REACH. Only limited data are required for substances produced or imported at a volume of 1-10 tpa (approximately 17,500 substances, or 60% of those that are subject to registration).

(2) Limited dossier review and validation—An electronic check will confirm the completeness of all dossiers submitted by chemical producers. However, only about 5% of dossiers in each tonnage band will be evaluated for compliance, a more thorough review of the data's relevance and accuracy. While the burden of providing information on targeted chemicals has been shifted to producers, the government will face an enormous task of evaluating the data quality.

(3) Limited Candidate List—To nominate SVHCs for the Candidate List, Member States or ECHA must prepare a dossier for each chemical. A rather cautious start by Member States to use the new provisions, combined with ECHA's limited capacity to review the dossiers produced an initial Candidate List of just 15 substances.[51] Meanwhile, the Swedish NGO, International Chemicals Secretariat (ChemSec) generated a list of 267 substances

[51] European Chemicals Agency, *Candidate List of Substances of Very High Concern brings new duties for companies*. ECHA/PR/08/38-REV. November 4, 2008, http://echa.europa.eu/doc/press/pr_08_38_candidate_list_20081028.pdf (Accessed March, 2009).

for which toxicologists deemed there was sufficient information to meet the criteria for SVHCs stipulated in REACH, suggesting that they would all be suitable for nomination for the Candidate List.[52]

(4) Thresholds for regulating substances in articles— Chemicals in articles must only be registered if they: (1) total more than 1 tpa per producer or importer, (2) are contained in articles in concentrations higher than 0.1% weight by weight, *and* (3) are intended to be released from the article during normal use. These limited requirements may shield many potentially hazardous substances from reporting.[53]

(5) Limited substitution requirements—Chemicals included in Annex XIV of REACH are in principle subject to mandatory substitution. However, if manufacturers can prove they can achieve "adequate control" for specific uses, or if they can prove that there are no suitable alternatives and the socio-economic benefits of continued use outweigh the risks, companies may gain authorization for their continued use.

It remains to be seen how significantly these potential limitations will affect the ability of REACH to effectively protect human and environmental health and promote the development of safer alternatives to hazardous substances.

VI. Policy implications

Global ecosystem contamination, biodiversity loss and threats to ecosystem services reflect the impacts of chemical and product management around the world. Implementation of the REACH regulation has informed and bolstered California's chemicals policy reform; it has provided model methods and structures, and it has forced change within a historically intransigent U.S. chemical enterprise. By controlling access to European markets, REACH sets what may become a *de facto* global standard for information disclosure. Additionally, its passage has introduced immediate economic pressures and an element of inevitability into California chemicals policy discussions.

Trade links between California and the EU are robust: in 2007, the EU reported that trade with and investment by the Europe earns California $63 billion annually and supports over one million jobs in the state.[54] As an export market for California, the EU earns the state $28 billion annually, making it twice as large as Japan and China combined, and California is the top U.S. exporting state to Europe.[55] Thus, Europe's recent slate of policies addressing chemicals and products has significant implications for California's businesses.

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[52] International Chemicals Secretariat, *Methodology for selection of substances included in the REACH SIN* List 1.0.* ChemSec, http://www.chemsec.org/documents/080917_SIN_List_methodology.pdf (Accessed March 2009).

[53] World Wildlife Fund, *Navigating REACH*. Brussels: August 2007, http://www.wwfint.org/about_wwf/what_we_do/policy/toxics/publications/index.cfm?uNewsID=115541 (Accessed March, 2009).

[54] The EU & California, "A Key Piece of a Thriving Economic Partnership," *EU Insight* 11 (2007): 1-2, http://www.eurunion.org/News/eunewsletters/EUInsight/2007/EUInsight-California2007.pdf. (Accessed March 2009).

[55] U.S. Census Bureau, "Foreign Trade Division," Updated figures available at: http://tse.export.gov/SEDChartDisplay.aspx?UniqueURL=pvmskbexpwn1ze45uivkpy45-2006-10-30-15-42-48 (Accessed March 2009).

The state's strong economic ties with Europe make engagement with these policies unavoidable: multinational businesses must comply with EU regulations or risk losing critical markets. Similarly, regions with more lenient standards than the EU face the prospect of becoming markets for hazardous goods prohibited in Europe.[56]

In addition to ecological benefits, the potential public health gains of REACH include an estimated savings of $60 billion over 30 years by preventing just a portion of occupational disease. [57] In the setting of nationalized health care, these savings accrue directly to the government, a fact that may have improved the viability of the REACH regulation in EU.[58]

Transatlantic learning to date

As important economic partners, and with similar health and environmental priorities, California and the EU have a history of collaboration on international issues. The EU has publicly recognized California as a policy leader and innovator in the U.S., particularly on the environment.[59] During a 2008 visit to California, EU Ambassador to the U.S. John Bruton addressed members of the state legislature and signed a Memorandum of Understanding with the Chancellor of the University of California, Berkeley, agreeing to support regulatory cooperation between California and the EU in areas such as biodiversity, climate change, green chemistry, and waste management.

In crafting its new chemicals policies, California is already looking to Europe for regulatory models, chemical lists developed under EU directives, and the data anticipated to become available under REACH.

The potential for continued transatlantic learning

With its ongoing Green Chemistry Initiative and recent passage into law of AB 1879 and SB 509, California has initiated the development a more comprehensive approach to chemicals policy. This is already producing a host of technical questions that will require new kinds of expertise, much of which is being developed in the EU. California's effort to lead the U.S. in chemicals policy would be bolstered by cooperation with the EU, through technical consultation, strategy development, and data exchanges.

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[56] M. Schapiro. Exposed: The Toxic Chemistry of Everyday Products and What's at Stake for American Power (White River, VT: Chelsea Green Publishing, 2007).

[57] European Commission. *Assessment of the Impact of the New Chemicals Policy on Occupational Health - Final Report.* United Kingdon, Norfolk: Risk and Policy Analysts Limited, 2003. http://ec.europa.eu/environment/chemicals/reach/background/docs/finrep_occ_health.pdf (accessed January 30, 2009).

[58] M. Schapiro, Regulatory Politics and Policies in the United States and Europe: Why the Difference? (Working Paper No. 66, presented at UC Berkeley Institute of Governmental Studies, February 20, 2008). http://igov.berkeley.edu/workingpapers/series4/schapirosketch.doc.

[59] John Bruton, "How European Trade and Investment Create Jobs and Business Opportunities in California" (Submission to the California Senate Select Committee, February 13, 2008). http://www.eurunion.org/welcome/ambassadorscorner/JB-CASenSelCttee-2-13-08.doc (Accessed March, 2009).

Likewise, public and environmental health advocates in the EU stand to benefit if California, in its own chemicals policy, addresses potential limitations of REACH. California has the opportunity to respond to the pressure created by both internal problems (such as the health, environmental and economic consequences of the chemical enterprise) and external forces (EU requirements and global market demand). Done well, this has the potential to 1) fuel global demand for safer substances, increasing the incentive for innovation in green chemistry, 2) contribute to improvements in human health, resource conservation and environmental protection, and 3) shift the U.S. into a position of greater collaboration in international sustainability efforts.

Mechanisms to advance transatlantic learning

California and the EU should pursue cooperation in the following ways:

Share Information

(1) *Access to Chemical Hazard Information*: California's new chemicals policy bill, AB 1879, authorizes state officials to draw on information available to other governments. Using this vehicle, the California Environmental Protection Agency's (Cal/EPA) Department of Toxic Substances Control (DTSC) should establish relationships with ECHA and the European Commission to enable access to chemical information submitted under REACH. As California companies (through their importers or only representatives in the EU) submit information to EU authorities, it will become increasingly untenable for those companies to withhold such data from Cal/EPA, U.S. EPA and the public. Although U.S. EPA has previously requested similar data from chemical producers, it lacks the legal authority to require disclosure, with the result that producers have submitted only limited information.

(2) *Chemicals in Articles:* Regulations under development for California's chemicals bill, AB 1879, will enable identification of certain "chemicals of concern" in consumer products. If the criteria for these chemicals of concern include the SVHC criteria, Europe stands to gain significant information—beyond the scope of REACH—on the presence of SVHCs in common products. A centralized access point for this information is essential if it is to serve the goal of reducing the use of the most hazardous chemicals.

(3) *Research collaborations:* Both California and the EU are attempting to fill existing gaps in information about health and environmental effects of chemicals. Increasing international collaboration on the research questions asked—and data generated— by publicly funded research projects could eliminate redundancies and significantly speed these efforts.

(4) *Biomonitoring:* While some Member States have significant information from decades-old biomonitoring research, in the last year, both California and the EU have initiated new biomonitoring programs.[60] Data generated by these programs on human exposure to synthetic chemicals and pollutants, will inform the process of prioritizing chemicals of concern. Sharing data will increase understanding of regional variations in chemical exposure and disease.

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[60] California Biomonitoring Program, http://www.dhs.ca.gov/ehlb/bpp/default.htm. European Human Biomonitoring http://www.eu-humanbiomonitoring.org/ (Accessed March , 2009).

(5) Collaborate with non-governmental organizations (NGOs): European NGOs were closely involved in all aspects of developing the REACH regulation. California can tap into their expertise. For example, among information available to both governments is the "SIN List 1.0"—the 267 substances identified by the Swedish NGO, ChemSec, as SVHCs. Because ChemSec identified these chemicals using the same criteria stipulated under REACH, this list can help both ECHA and DTSC identify and prioritize chemicals for immediate action or further investigation.

Share Best Practices

Implementing a chemicals policy such as REACH requires regulatory agencies as well as affected business to address a host of technical questions. ECHA and DTSC will have to address distinct issues relevant to implementing their own regulations. The two agencies should establish a means of sharing best practices on such issues as:

(1) Developing chemical and product life-cycle assessment tools that minimize risk-shifting among environmental media while remaining efficient and widely applicable.

(2) Developing methods of assessing alternatives to chemicals of concern, addressing the problems inherent in weighing relative hazards, evaluating emerging science, and making decisions under conditions of uncertainty.

(3) Performing cost-benefit analyses for regulations that encompass the costs to society incurred from human disease, environmental harm and loss of ecosystem services.

(4) Providing reasonable protection for confidential business information, while ensuring that key information such as chemical identity and hazard traits remains public.

(5) Building an appropriate information technology (IT) infrastructure for access to information on product ingredients, chemical use and hazard traits.

Contribute to International Efforts

Harmonize regulations: The implementation of REACH, California's new laws, and the prospect of impending TSCA reform at the U.S. federal level, risks producing a patchwork of chemical regulations, thereby creating markets for substandard goods, as well as burdensome compliance issues for multinational companies. The efficiencies that can occur with harmonization of regulations, where appropriate, will benefit the public, businesses, industry and government.

Join the international environmental community: California should encourage the U.S. government to support a multinational environmental agenda by such actions as ratifying the Stockholm Convention on Persistent Organic Pollutants, the Basel Convention on the Control of Trans-boundary Movements of Hazardous Wastes and Their Disposal, and the Convention on Biological Diversity.

VII Conclusion

Synthetic chemicals and pollutants, including many EDCs, are now ubiquitous environmental contaminants, and evidence points to their association with declining biodiversity and the provision of ecosystem services.

The EU has assumed global leadership—through enacting the REACH Regulation—in environmental stewardship and regulatory stimulus toward the design, production, and use of safer chemicals and products. The U.S. must now follow suit in order to improve human and ecosystem health, fuel global demand for safer substances, position the U.S. to better satisfy that demand, and boost the nation's participation in international sustainability efforts.

Within the U.S., California is beginning this task, in its historic role as bellwether for the nation in environmental regulation. The state's 2007 Green Chemistry Initiative[61] and two laws enacted in 2008[62] are the first step toward a more comprehensive policy.[63] How these laws are implemented will determine whether California joins the EU, or cedes to others both market share and the opportunity for implementing critical environmental protection.

While the U.S. has largely lost its stature as a global leader in environmental policies, California has a record of tackling complex environmental issues with policy reforms that link economic development with improvements in human health and ecosystem protection. The contrast between existing federal chemicals policies and the new regulatory approach adopted by the EU offers an unprecedented opportunity for a two-way exchange between California and the EU. Forging links with the EU will facilitate California's process and could provide EU policymakers a footing for strengthening REACH in subsequent negotiations. Transatlantic cooperation could thus speed the development of comprehensive new chemicals policies, and California has the chance to play a leading role in addressing critical global environmental problems.

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[61] California Department of Toxic Substances Control, http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/index.cfm (Accessed March 2009).

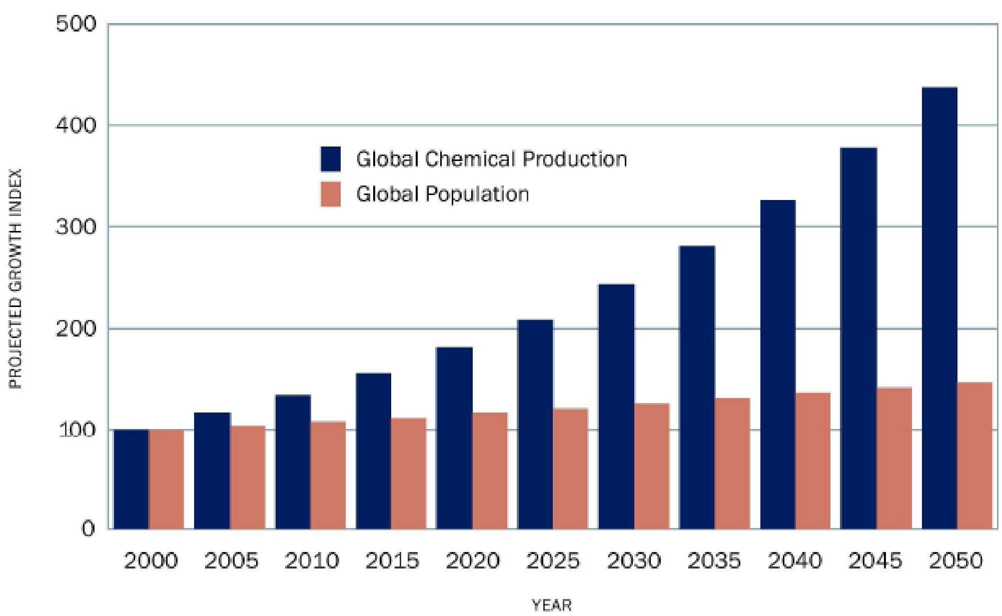
[62] US Congress. Senate. *An act to add Sections 25252, 25252.5, 25253, 25254, 25255, and 25257 to the Health and Safety Code, relating to hazardous materials.* Assembly Bill 1879 (September 29, 2008). http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1851-1900/ab_1879_bill_20080929_chaptered.pdf (accessed March 2009). US Congress. Senate. Senate Environmental Quality Committee. *Consumer products: content information.* Senate Bill 509 (Jan. 14, 2008). http://www.leginfo.ca.gov/pub/07-08/bill/sen/sb_0501-0550/sb_509_bill_20080929_chaptered.pdf (Accessed March 2009).

[63] M. R. Schwarzman, M. P. Wilson, "Op Ed: California's new chemical laws: Good start, need work," *Environ Health News* (October 2008), http://www.environmentalhealthnews.org/ehs/editorial/california-takes-bold-new-steps-in-addressing-weak-chemical-policies

Table 1. While TSCA applies to tens of thousands of substances, only 1,134 chemicals and pollutants are listed by other U.S. statutes. *Source: J. Dernbach, "Unfocused Regulation" 1997.*

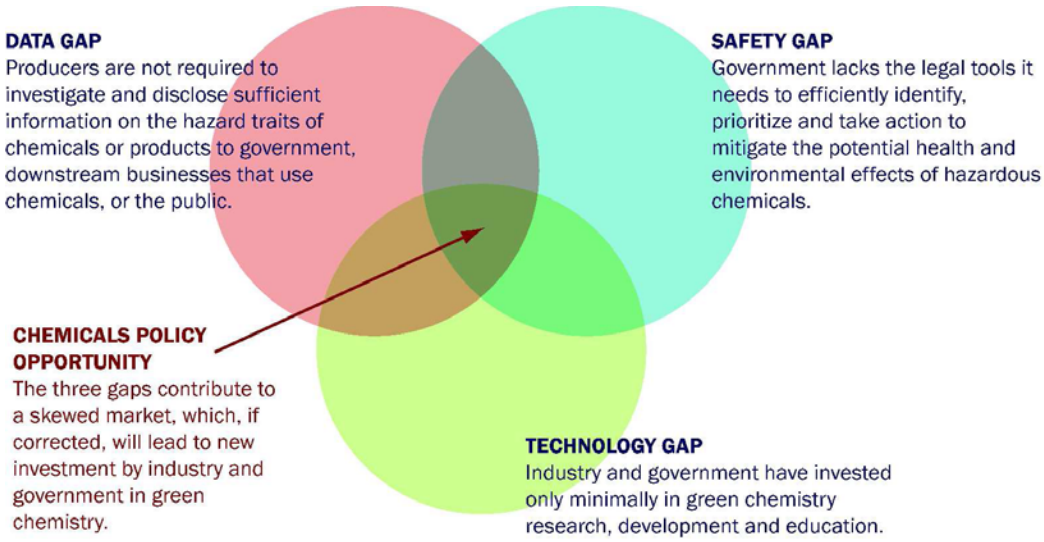
Federal statute	Number of chemicals
Clean Water Act (CWA)	148
Resource Conservation and Recovery Act (RCRA)	502
Clean Air Act (CAA)	189
Occupational Safety and Health Act (OSH Act)	453
Emergency Planning and Community Right-to-Know Act; Toxics Release Inventory (EPCRA–TRI)	600

Figure 1. Projected global chemical production relative to population growth. *Source: Wilson and Schwarzman, "Toward a New Chemicals Policy" 2009.*



Global chemical production is projected to grow at a rate of 3% per year, rapidly outpacing the rate of global population growth, estimated at 0.77% per year. On this trajectory, chemical production will double by 2024, indexed to 2000.

Figure 2. U.S. Chemicals Policy Gaps *Source: Wilson and Schwarzman, "Toward a New Chemicals Policy" 2009.*



The three gaps in U.S. chemicals policy: Data Gap, Safety Gap and Technology Gap. Policy measures that address the gaps will promote sustainable innovation in the chemical enterprise while improving human health and the environment.

Figure 3. Spectrum of levels of evidence as the basis for decision-making *Adapted from: M. Wilson et al. Green Chemistry in California: Framework for Leadership and Innovation, University of California Regents, 2006.*