SCIENCE AND REGULATION

New Science for Chemicals Policy

U.S. regulation of chemicals is in need of an overhaul, informed by European legislation and guided by new thinking about risk.

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Over the last century, industrial chemicals have become ubiquitous in materials, products, and manufacturing processes used throughout society. In 2006, more than 34 million metric tons of chemical substances were produced in, or imported into, the United States every day (*1*). Over the next quarter-century, global chemical production is projected to double, rapidly outpacing the rate of population growth (*2*). These substances ultimately enter Earth's environment; hundreds of chemicals are routinely detected in people and ecosystems worldwide (*3*, *4*). Long-standing public policies governing chemical design, production, and use need deep restructuring in light of new science on the health and environmental effects of anthropogenic chemicals. Such reforms are essential to safeguard ecosystem integrity, human health, and economic sustainability.

Gaps in U.S. Chemicals Policy

The U.S. Toxic Substances Control Act (TSCA) is the primary mechanism by which the Environmental Protection Agency (EPA) is expected to oversee more than 80,000 chemicals. Just over 1000 of these substances are regulated by other major U.S. environmental statutes (e.g., the Clean Water Act) (*5*). But most health and ecological risks associated with industrial chemicals are still poorly understood because TSCA, like policies of many other nations, does not require producers to generate basic information on chemical uses, health effects, or exposures (*6*). The default assumption is that chemicals remain on the market unless or until government generates sufficient evidence to prove harm. Even then, chemicals policies worldwide have failed to grant governments sufficient means to control most chemicals, including those whose risks are well-established. It is a testament to the limitations of TSCA that, since 1976, the EPA has been able to apply the statute in regulating just five substances (*6*). Such failings have been documented for decades (*7*), yet the absence of federal action to date means that chemicals policy reform remains an urgent societal need (*8*). In response, some U.S. states are developing their own approaches to chemical regulation (*9*).

The lack of transparency and accountability in the chemicals market has hidden many human and environmental costs of chemical exposures. As a result, the market essentially "undervalues" the safety of chemicals relative to their function, price, and performance. Producers have thus had little incentive to develop safer substances according to the principles of green chemistry.

Ecosystems and Endocrine Disruption

The lack of well-functioning chemicals policies worldwide has contributed to extensive ecosystem contamination by anthropogenic chemicals. These include hundreds of endocrine-disrupting chemicals (EDCs) whose distinct hazard traits are transforming our understanding of chemical risk. Many EDCs, such as polychlorinated biphenyls, phthalates, and bisphenol A, interfere with biological signaling mechanisms that govern development, reproduction, or immune function in humans and wildlife (*10*, *11*). EDCs have also been linked with population declines due to invertebrate imposex (masculinization or feminization); egg-shell thinning in birds and reptiles; and reduced reproductive capacity and immune function in fish, mammals, and amphibians (*12*). Many EDCs persist in the environment and biomagnify in higher trophic levels.

Improved understanding of the unique characteristics and impacts of EDCs upends many tenets of risk assessment on which chemicals policies are currently based. When exposures occur during critical periods of development, EDCs can produce lifelong, sometimes multigenerational, changes, which suggests that risk assessment should account for timing of exposure in addition to dose (*13*). Some EDCs are most potent at concentrations several orders of magnitude lower than those tested by toxicological methods commonly used for regulatory purposes. EDCs in combination can produce additive or synergistic effects (*14*) that cannot be predicted by assessing individual chemicals in isolation. Some hormone alterations caused by EDCs might appear slight in an individual but can have potentially large population-level effects (*15*) by reducing intelligence, reproductive capacity, or disease resistance.

EDCs demonstrate the contribution of chemical pollution to a set of interrelated factors, including biodiversity loss and climate change, that affect ecosystem resilience and threaten societal sustainability (*16*). Translating the emerging science of endocrine disruption into chemicals policy will require new toxicological tools and cumulative risk assessment methods (*17*). It will also demand a fundamentally new way of thinking about the risks associated with chemical exposures, one in which precaution informs the application of scientific evidence to public policy. This approach would acknowledge scientific uncertainty and the potential to deliver as-yet-unrecognized hazards to future generations (*18*). In practical terms, this will require that producers demonstrate the safety of a chemical as a condition of its use, and that governments have the means of acting on early indications of harm.

A More Precautionary Policy: EU's REACH

The U.S. approach to chemicals policy has fallen behind global changes, led by the European Union (EU). Most important among the EU's new legislation is the 2006 regulation on the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) (*19*). A core structural difference between REACH and TSCA is the European law's requirement that chemical manufacturers and importers, not the government, provide basic information on the identity and physical properties of ~30,000 chemicals sold in volumes of more than one metric ton per year, per producer. More comprehensive hazard data are required for a subset of ~12,000 substances whose sales exceed 10 metric tons per year.

REACH further designates some chemicals as Substances of Very High Concern (SVHCs) on the basis of properties such as environmental persistence and bioaccumulation, or because they are classified under EU law as carcinogens, mutagens, or reproductive toxicants. Authorization for continued use of these highest-risk chemicals will hinge on producers' demonstrating the safety of each intended use, or that, in the absence of suitable alternatives, the socioeconomic benefits outweigh the health and environmental risks. How these risks and benefits are calculated will determine the degree of health protection afforded by the authorization provision

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CORE DISTINCTIONS BETWEEN CHEMICALS POLICIES OF THE UNITED STATES (TSCA) AND THE EUROPEAN UNION (REACH)

	TSCA	REACH
Burden of proof	Producers are not required to generate and disclose hazard data; government bears the burden of proof of harm.*	Producers must (i) supply hazard data for eligible chemicals on the basis of volume in commerce and (ii) demonstrate safety or adequate control of certain chemicals of concern.
New chemicals	Producers must submit premanufacture notification, but there is no minimum required set of hazard data.	Chemicals introduced since 1981 are subject to volume-based data requirements.
Existing chemicals	Chemicals in use before 1976 were assumed to be safe and were not subjected to the regulation.	Chemicals in use before 1981 are subject to the same volume-based data requirements as new chemicals.
Prioritizing chemicals for regulatory action	The lack of data requirements precludes effective prioritization.	Chemicals are prioritized by hazard and exposure potential; chemicals of concern are subject to use-by-use authorization.
Supply chain transparency	No requirements.	Two-way flow of hazard and exposure information is required between chemical producers and commercial users.
Public access to information	Extensive trade secret claims are allowed, including chemical names and uses.	A database of registered chemicals with clear criteria for trade secret claims will allow public access to a yet-to-be-determined body of information.

*TSCA does give EPA authority to require a producer to test a chemical for health and environmental effects. But EPA must first establish that the substance poses "an unreasonable risk" to human health or the environment, or that there is either significant environmental release or human exposure potential. These restrictions in the statute place EPA in a logical paralysis: to require information for assessing a chemical's risk, EPA needs risk information that producers are under no obligation to provide.

of REACH. The regulation also provides a means of controlling substances not otherwise classified as hazards, such as EDCs, by creating a category of SVHCs called "substances of equivalent concern." Finally, REACH gives government the ability to regulate a substance irrespective of its toxicity, based instead on its designation as "very persistent, very bioaccumulative." REACH is thus the first comprehensive chemicals policy to codify a precautionary approach to some chemicals whose risks are not yet fully understood.

In addition to the anticipated (but not-yet-quantified) ecological benefits of reduced environmental contamination, REACH is expected to garner significant public health gains. Savings of $60 billion are predicted over 30 years due to prevention of occupational diseases alone (*20*). By improving overall transparency and accountability in the chemicals market, REACH is also expected to advance green chemistry innovation.

International Impact

By placing conditions on access to European markets, REACH has set what may become a de facto global standard. The influx of chemical information expected under REACH, as well as the potential for countries outside Europe to become markets for toxic substances prohibited in the EU, presents other regions with an opportunity, and imperative, to retool their chemicals policies.

In the fall of 2009, the Obama Administration unveiled principles for U.S. chemicals policy reform, proposing that chemical producers be required to submit sufficient hazard, exposure, and use data for EPA to determine that chemicals meet a health-based safety standard (*21*). The principles further acknowledge the EPA's need for authority to act on priority chemicals, reducing risks they pose to sensitive subpopulations. These principles could influence development of TSCA reform. If implemented, they could improve EPA's ability to protect public health and the environment, while also providing the necessary incentive to move the chemicals market toward green chemistry, with the ultimate goal of placing the U.S. chemical industry on a more sustainable footing.

Toward an Integrated Chemicals Policy

New chemicals policies must confront multiple challenges: a backlog of unexamined chemicals; ineffective means of phasing out chemicals of concern; and the need for methods to apply emerging science on chemical hazards, such as EDCs, to inform precautionary decision-making. New approaches should enable action in the face of scientific uncertainty and should account for interrelated factors affecting human health and ecosystems. Well-intentioned environmental regulation has been plagued by the substitution of one hazard for another, such as the shifting of chemical risks from air to water, from the general population to workers, or from energy solutions to chemical hazards. No one policy can single-handedly prevent these missteps, but the next generation of environmental decision-making can better reflect interconnectedness in nature and society.

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