DRIVING INNOVATION

How stronger laws help bring safer chemicals to market

CIEL
Center for International Environmental Law

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About CIEL

Founded in 1989, the Center for International Environmental Law (CIEL) uses international law and institutions to protect the environment, promote human health, and ensure a just and sustainable society. CIEL's staff of international attorneys work in the areas of toxic chemicals, human rights and the environment, climate change, law and communities, trade and the environment, international environmental governance, biodiversity and international financial institutions by providing legal counsel and advocacy, policy research and capacity building.

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Contents

Acronyms

ACC	American Chemistry Council
BBP	Benzylbutylphthalate, also called n-butyl benzyl phthalate or benzyl butyl phthalate
CBI	Confidential Business Information
CFC	Chlorofluorocarbon
CIEL	Center for International Environmental Law
CMR	Carcinogenic, mutagenic or toxic to reproduction
CPSC	Consumer Product Safety Commission
DBP	Dibutyl phthalate
DEHP	Bis(2-ethylhexyl) phthalate
DIBP	Diisobutyl phthalate
DINP	Diisononyl phthalate
DINCH	1,2-cyclohexane dicarboxylic acid diisononylester
DPHP	Bis(2-propylheptyl) phthalate
ECHA	European Chemicals Agency
EDC	Endocrine disrupting chemical
EDDS	Ethylenediamine-N,N′-disuccinic acid
EDTA	Ethylenediaminetetraacetic acid
EU	European Union
HaSDR	Health and Safety Data Reporting
HCFC	Hydrochlorofluorocarbon
HFC	Hydrofluorocarbon
NOAEL	No observed adverse effect level
NPE	Nonylphenol ethoxylate
PBB	Polybrominated biphenyl
PBDE	Polybrominated diphenyl ether
PBT	Persistent, bioaccumulative and toxic
PCB	Polychlorinated biphenyl
PVC	Polyvinyl chloride
R&D	Research and development
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SMEs	Small- and medium-sized enterprises
SVHC	Substance of Very High Concern
SDS	Safety Data Sheet
TBPH	Bis(2-ethylhexyl)-2,3,4,5-tetrabromophthalate
TBB	2-ethylhexyl-2,3,4,5-tetrabromobenzoate
TPP	Triphenyl phosphate
TSCA	Toxic Substances Control Act
UNEP	United Nations Environment Program
U.S.	United States
vPvB	Very Persistent and Very Bioaccumulative
WHO	World Health Organization

Executive Summary

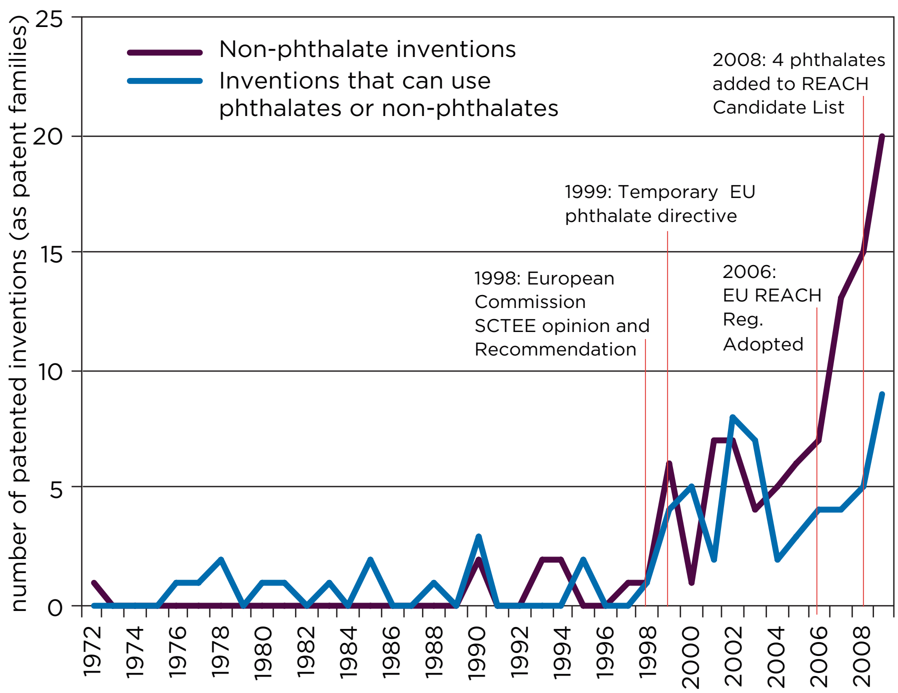
Are innovation and the law at odds? A closer look shows that stronger laws* for the management of hazardous chemicals help to drive innovation in chemical and product sectors. Innovation is especially relevant today as the US$ 4.1 trillion (2.5 trillion euro) global chemical industry faces increasing pressure from consumers, retailers, and investors demanding safer products. At the same time, emerging economies are increasingly well-positioned to become leaders in chemical innovation, potentially leaving Western Europe and the United States behind. Together, all of these forces are instigating changes in how governments, chemical manufacturers, and downstream users of chemicals are working to ensure chemical safety and drive innovation.

The Center for International Environmental Law (CIEL) examined the impact of laws governing hazardous chemicals in terms of their effect on innovation.

Our study finds that stricter rules over hazardous chemicals can not only drive innovation, but also create a safer marketplace.

FIGURE ES 1

Spike in Patented Inventions Free of Hazardous Phthalates



Exponential growth in the number of patented inventions for phthalate alternatives beginning in 1999, coinciding with the adoption of stricter rules (as captured by the number of patent families for "non-phthalate" and "phthalate free" inventions)

The prospect of stricter laws with regard to toxic chemicals sparked the invention, development, and adoption of alternatives. For example, in response to stricter laws to protect people and the environment from phthalates, a class of chemicals with hormone (endocrine) disrupting properties, our study of international patent filings shows acceleration in the invention of alternative chemicals and products. Spikes in the patenting of phthalate-alternatives clearly correlate with the timing of new laws to protect people and wildlife from phthalates. As the stringency of measures increased, so too did the number of inventions disclosed in patent filings by the chemical industry. Similarly, the phase-out of ozone depleting substances also illustrates how progressively stricter rules at the global level can drive a sustained effort to invent safer alternatives.

As innovation hinges on the adoption of inventions, stricter laws for hazardous chemicals can also help to pull inventions into the market, turning an invention into innovation, as our case studies highlight. Barriers exist that prevent the entry of safer alternatives. Overcoming the inertia of entrenched toxic chemicals typically requires the power of the government. Our findings show that stricter laws enable safer chemicals to overcome barriers to entry, such as economies of scale enjoyed by the current mix of chemicals, the externalization of costs, and the lack of information about chemicals and products on the market today.

However, history is replete with examples of regrettable substitution, where a hazardous chemical is restricted, but then replaced with a different hazardous chemical. The experience of transitioning from one hazardous flame-retardant chemical to

* We define "laws" to include legislation, regulation, directives, decisions, rules, and other forms of enforceable standards at the sub-national, national, regional and global levels.

another illustrates not only the dangerous presumption of safety about chemicals on the market for decades, but also the weakness of programs to evaluate recently developed chemicals for their hazardous properties.

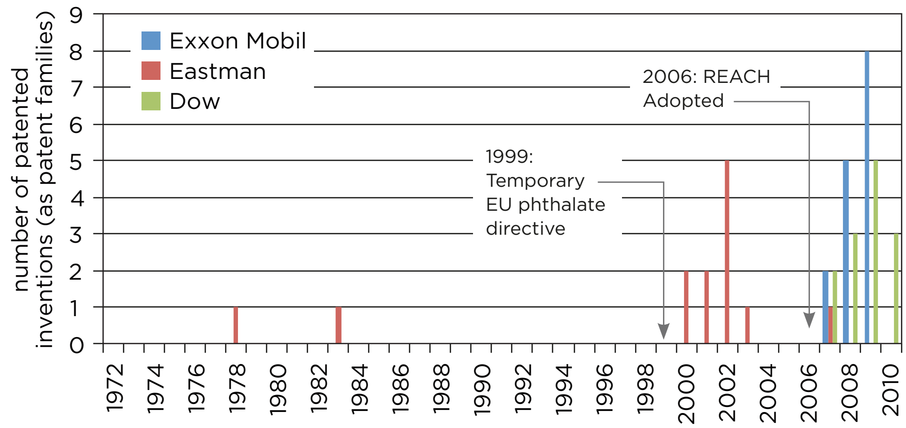
We also found examples of alternative chemicals with a high-degree of structural similarity to the hazardous chemicals they replaced, with inadequate information about the alternative's potentially hazardous properties. For example, alternatives to hazardous chemicals entered the market with a startling lack of publicly-available information about their hazards. Some of these alternative chemicals are structurally similar to previously restricted chemicals around the world. However, under existing laws, additional information took many years to be requested, let alone generated.

In order to increase the likelihood that safer alternatives will be pulled into the market, chemical laws need to clearly identify hazardous properties that are not acceptable in society, generate information about these properties in all chemicals, and require their substitution with safer alternatives in a systematic way. Stricter laws can enable a transition to safer alternatives.

In short, progressively stricter laws spur the innovation of safer alternatives and can pull safer alternatives into the market, enabling them to overcome barriers to entry. But, policies must be in place to ensure that alternatives do not also have intrinsic hazards, to better ensure that innovation creates a safer marketplace. To this end, CIEL provides the following recommendations for policy makers in Europe, the United States, and other countries and regions around the world:

FIGURE ES 2

Stricter Laws Trigger Innovation by Major Chemical Manufacturers



Number of patented inventions by Eastman Chemical (formerly Kodak Eastman), Exxon Mobil and Dow Chemical from 1972–2010 for phthalate alternatives.

1. Ensure the burden of proving chemical safety falls on chemical manufacturers

Requiring that chemical manufacturers generate information about the intrinsic hazards of both existing as well as new chemicals levels the playing field for safer chemicals and enables a more meaningful assessment of alternatives. This information enables regulators to remove entrenched chemicals of concern, downstream users to deselect hazardous chemicals from their supply chain, and chemical manufacturers to innovate towards safer alternatives. Although recent progress has been made, most notably in Europe, in placing the burden of proving chemical safety on chemical manufacturers, greater measures are needed, particularly in countries such as the United States that have not updated outdated chemical policies from the 1970s and others that do not have such policies in place.

2. Phase-out chemicals with certain intrinsic hazards

Government authorities must possess—and exercise—the power to remove hazardous chemicals from the market based on their intrinsic hazards.

3. Recognize endocrine disruption as an intrinsic hazard that cannot be soundly managed

Endocrine disruption is an intrinsic hazard of certain chemicals, linked to a myriad of adverse effects that have been on the rise over the past several decades. As there is no safe dose of exposure to endocrine disrupting chemicals (EDCs), they should be recognized as a distinct category of chemicals that needs to be phased out globally, similarly to other chemicals with intrinsic hazards.

4. Internalize the costs of hazardous chemicals

Not only would this lead downstream users to shift to alternatives with lower costs, but this would in turn incentivize chemical manufacturers to invest in the research and development of safer alternatives.

5. Promote access to information

Inventors need access to information about chemical hazards and exposures to develop safer solutions. Regulators need access to hazard and exposure information to restrict the use of hazardous chemicals, enabling the entry of safer alternatives. Consumers and downstream users need access to information about chemicals in products throughout the supply chain to enable them to choose safer products, thereby incentivizing innovation toward safer alternatives. Policy makers should ensure that health and safety information is generated and made available to consumers, businesses, and regulators, including awareness of products containing hazardous chemicals. Claims of confidentiality should be justified, periodically re-justified, and never granted for health and safety information, to enable the development of safer alternatives.

6. Craft stronger international laws to ensure a level playing field at the global level

Only a narrow sliver of chemicals of concern on the market are covered under legally binding global treaties throughout their lifecycle. A broader international regime to cover a wider range of hazardous chemicals and chemical-related risks is required to create a level playing field for businesses operating in a globalized world.

CHAPTER 1

Introduction

No one can deny that many of the features of modern life owe much to the ingenuity of the chemical industry. New chemicals, new applications for existing chemicals, and new chemical processes enabled a host of innovations across a range of industries, and led to the growth of the chemical industry over the past several decades. Since the 1970s, the output of the chemical industry has grown from approximately one trillion U.S. dollars adjusted for inflation, to US$ 4.12 trillion in 2010, with estimates for 2020 approaching US$ 6.5 trillion.[1] As the scale of the chemical industry has grown, so too has evidence of the adverse effects of chemicals on human health and the environment.

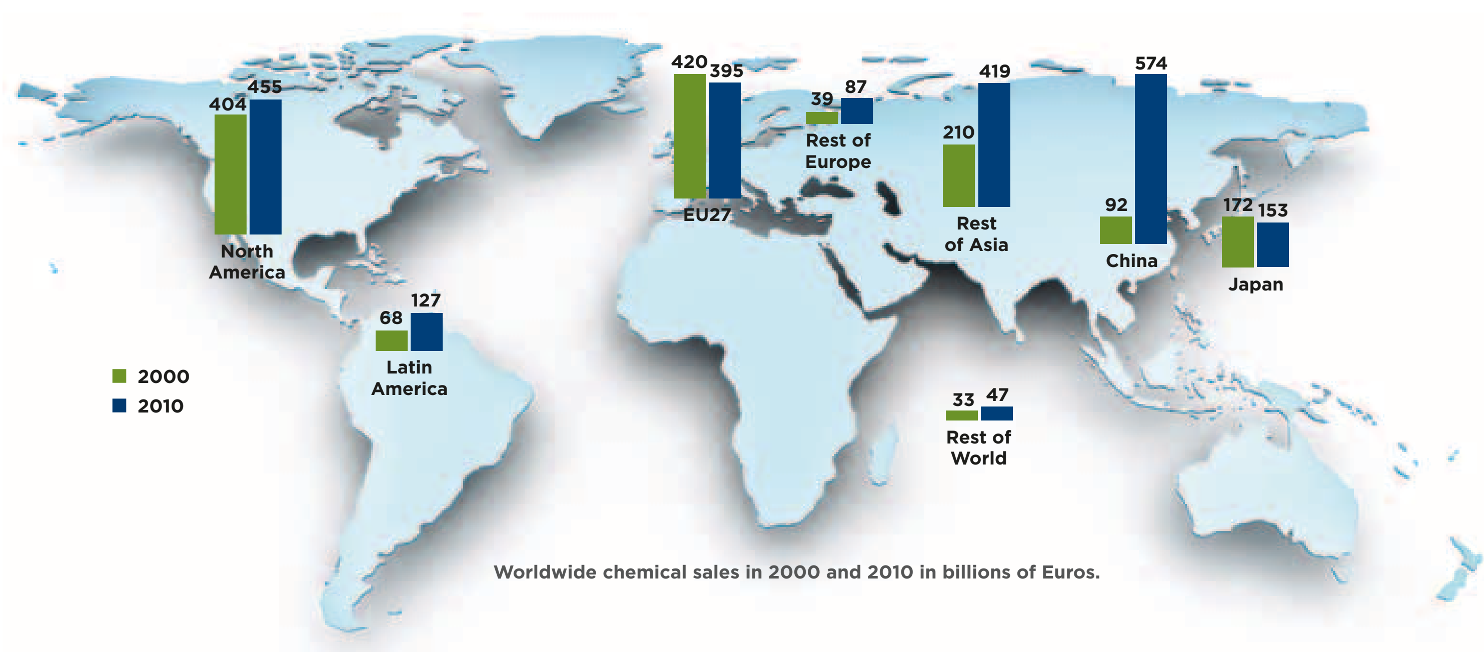
Innovation is especially relevant today as the establishment of the chemical industry, from manufacturers to formulators, face increasing pressure from two fronts.[2] First, after overtaking traditional leaders such as the United States and Western Europe in bulk chemical manufacturing, emerging economies are positioning themselves to become leaders in chemical innovation (see Figure 1).[3] Simultaneously, the chemical industry is also facing increasing pressure from downstream users, retailers and consumers to provide safer products through the development and use of safer chemicals (see Box 1, page 4).

> ***"… Laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths discovered and manners and opinions change, with the change of circumstances, institutions must advance also to keep pace with the times."***
>
> Thomas Jefferson, principal author of the Declaration of Independence and third President of the United States, July 12, 1816

A common refrain by the regulated (or soon-to-be regulated) industry is that stricter laws over hazardous chemicals will impede innovation, reducing economic growth, competitiveness, and employment. We define "laws" to include legislation, regulation, directives, decisions, rules, and other forms of enforceable standards at the sub-national, national, regional and global levels. Current laws in the European Union and United States designed to protect people and the environment from hazardous chemicals aim to enhance innovation.[4] However, both European and American laws have shortcomings in terms

FIGURE 1

Growth of Chemical Industry in Emerging Economies from 2000 to 2010



Source: CEFIC Facts and Figures 2011

of their ability to prevent harm, the costs of which are borne by individuals and society-at-large, and encourage the entry of safer alternatives. Can stricter laws over hazardous chemicals drive innovation? Can it drive innovation while also sending it in a safer direction?

The Center for International Environmental Law (CIEL) is examining the impact of past efforts to protect human health and the environment from hazardous chemicals in terms of their effect on innovation, and applying lessons to ongoing efforts to reform chemicals policy at the national, regional, and global levels. We studied recent measures to reduce the risk of harm from additives to plastics (phthalates), toxic flame retardant chemicals (PBDEs), refrigerants (CFCs), and pesticides (methyl bromide). Of particular interest were the features of policies that stimulated innovation and the factors that led to satisfactory or unsatisfactory outcomes. We examined patents as an indica-

> ***"Over-regulation . . . is seen as an old problem and there is a lot of truth in that. We are working to overcome it. But we also need to recognize that regulation can be a big driver of innovation. This is particularly the case in the environmental arena."***
>
> Peter Droell, Head of Innovation Unit, European Commission

BOX 1

Human Health Effects Linked to Hazardous Chemicals

As the scale of the chemical industry has grown since the 1970s, so too has evidence of the adverse effects of chemicals on human health and the environment.

Analyses of household cleaners, plastic products (including toys), clothing, and other everyday products show that many such products can contain over 70 chemicals considered of very high concern.[5] Recent biomonitoring studies confirm the migration of hundreds of hazardous chemicals from everyday products into people, either directly, or through food, water, air, household dust, and other sources.[6] Of significant concern is the exposure of children to a potent cocktail of hazardous chemicals during critical windows of development. These exposures occur through their mother's womb and breast milk, as well as from broader environmental sources mentioned above. The effects of exposure to these chemicals at an early age often do not manifest for many years or even decades.

There is an increasing incidence of many diseases around the world, including many that were much less prevalent in children in decades past. These trends include:

- A 20% increase of childhood cancers such as leukemia and brain cancer since 1975 and a 40% increase in the incidence of breast cancer between 1973–98;
- Asthma, which approximately doubled in prevalence between 1980 and 1995, continues to rise;
- 40% more women reported difficulty conceiving and maintaining a pregnancy from 1982 to 2002. From 1982 to 1995, the incidence of reported difficulty almost doubled in younger women, ages 18–25;
- Sharp increases in male genital malformations;
- Learning and developmental disabilities, including autism and attention deficit hyperactivity disorder, affect nearly one in six U.S. children, as of 2008;
- Doubling of the rate of diabetes in the United States and England, with increasing frequency among young populations; and
- Dramatic rise in the prevalence of obesity among both older and younger populations, and both wealthy, industrialized countries as well as poorer developing countries.[7]

There is growing consensus about the role of chemicals in the increasing incidence of many disorders around the world. Among many factors, there is increasing evidence that exposure to endocrine disrupting chemicals (see Box 3) at an early age is linked to many of these disorders.[8] Epidemiological data suggests EDCs may be contributing factors to increasing incidence of these diseases over the past several decades.[9]

BOX 2
Consumer Demand for Safer Chemicals

In response to consumer concerns and advocacy campaigns, reatilers and producers of consumer products are increasingly demanding other businesses in the value chain ensure that their products are free of hazardous chemicals.

Global clothing brands, Nike, Addidas, H&M, Zara and others recently announced plans to remove certain hazardous substances from their supply chain by 2015 or 2020, depending on the chemical. Among hazardous chemicals tested and found in garments were phthalates, nonylphenol ethoxylates (NPEs), and certain amines linked to cancer.

Johnson & Johnson announced plans to remove certain chemicals of concern from most of its adult toiletries and cosmetic products. By 2015, Johnson & Johnson will also phase out phthalates, as well as parabens and triclosan and certain fragrance ingredients, which aren't disclosed on product labels. However, two chemicals linked to cancer—1,4 dioxane and a formaldehyde-releasing chemical—will continue to be used where safe alternatives are not available.

According to Johnson & Johnson's Susan Nettesheim, Vice President of Product Stewardship and toxicology, "there's a very lively public discussion going on about the safety of ingredients in personal care products. . . . It was really important that we had a voice in that. . . . We want people to have complete peace of mind when they use our products."[10]

But, businesses that take the lead in developing and using safer chemicals are calling on policy-makers to craft policies that help to level the playing field, both at home and at the global level. For example, during a U.S. Senate hearing on the need for stricter laws in the United States, a major chemical formulator, stated: "We believe it is essential for the U.S. chemical management system to keep pace with global developments . . . and that our government be a global leader in chemical regulatory policy."[11] Major chemical manufacturers also call for a level playing field globally, with common definitions and standards, which do run the risk of harmonization to the weaker standards. But, certain chemical manufacturers, recognizing that the European Union's REACH Regulation is currently the "best in class," claim that "it would be very helpful if we could take our [chemical registration information required under EU regulations] and give it to Chinese authorities."[12]

Thus, businesses recognize that consumer demand alone is generally insufficient and government action may be required to enable safer alternatives to enter and compete on a level playing field, both at home and abroad.[13]

tion of rates of invention, and explored the types of inventions that were subsequently adopted by downstream users and consumers in the market.

Below we present some of our findings regarding the efficacy of past measures and the potential of stricter laws to accelerate innovation toward safer chemicals. First we present findings about the rate at which alternatives are invented in response to the prospect of stricter laws. Then we examine the types of inventions adopted by downstream users after measures are taken by regulators, exploring why the transition may or may not have been to safer alternatives. Third, we look at how the law can help safer alternatives overcome barriers to their entry, enabling early adopters to gain competitive advantage through innovation and an opportunity to optimize their return on new investments. The final section presents findings on how stricter laws direct resources to the innovation of safer alternatives. This study concludes with recommendations for policymakers to help drive innovation and send it in a safer direction.

CHAPTER 2

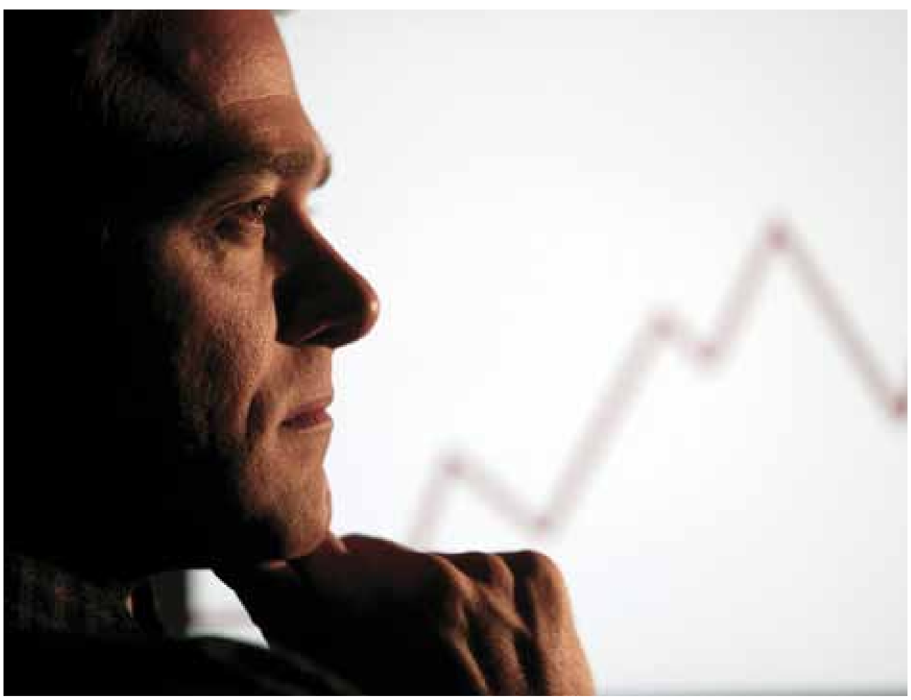
Stricter Chemical Laws Spark the Invention of Alternatives

A common argument against the prospect of stricter rules to protect people and the environment from hazardous chemicals is that there is not a viable alternative to the chemical. This argument might be made for technical reasons, such as the "performance" of the chemical relative to alternatives, or the lack of manufacturing capacity for alternatives. It can also be made for economic reasons, where an alternative is argued to be prohibitively expensive. Restricting or banning the chemical of concern would, the argument goes, reduce the competitiveness of a product or may even result in the unavailability of a product or process from the market altogether. The argument is essentially a threat of lost profits, jobs, and competitiveness at the global level.

These arguments, however, ignore our ability to invent better solutions and redesign the way people interact with their environment. We analyzed chemicals of concern, ranging from industrial chemicals in consumer products to pesticides, under national, regional and global environmental laws.

Our sample size was limited to chemicals that have sufficient information about their hazardous properties and are subject to significant scrutiny in more than one region of the world. In each case, the prospect of stricter rules for certain chemicals sparked the invention and development of alternatives, including improvements in the performance of pre-existing alternatives.[14] Stricter laws are defined as those the either: (a) require a significant reduction in exposure to hazardous chemicals; (b) require compliance through the use of comparatively costly technology; or (c) require significant technological change.[15] Below we present findings for two chemicals or classes of chemicals of concern that also clearly illustrate this trend: phthalates, a widely used endocrine disrupting chemical; and chlorofluorocarbon (CFC) refrigerants, ozone depleting substances.

The prospect of stricter rules for certain chemicals sparked the invention and development of alternatives, including improvements in the performance of pre-existing alternatives.



Stricter laws drive the invention of alternatives to phthalates

Phthalates are a class of chemicals used as plasticizers to soften certain plastics. Ninety percent of phthalate production, estimated to be in the millions of tons per year, is used to plasticize polyvinyl chloride (PVC).[16] As a plasticizer, phthalates are not bound to the plastic polymer, resulting in exposure for people and wildlife as they leach out of products, contaminating homes and the environment. Phthalates are also used as solvents in many cosmetics that are applied directly to the skin, including perfumes, lotions, soaps, shampoos, deodorants, and hair care products.

Certain phthalates are widely recognized as EDCs. Some disturbing genital deformations associated with phthalate exposure in animals have earned the title of "phthalate syndrome."[17] Other potential adverse effects include cancer, obesity, diabetes, and attention-deficit hyperactivity disorder.[18] Like other EDCs, these effects are believed to correlate with exposure during critical windows of development (see Boxes 1 and 3). Recent studies have detected phthalate metabolites in a high percentage of people tested. In some cases, phthalate metabolites were found in all of the urine samples analyzed.[19]

Beginning in 1998, following European leadership, countries around the world took measures to protect human health from certain hazardous phthalates. In addition

BOX 3

Endocrine Disrupting Chemicals

The endocrine system is the system of glands, each of which secretes different types of hormones directly into the bloodstream to regulate the body. Hormones regulate various biological functions, including human development, metabolism, cognition, the immune system, mood, sexual reproduction, and programmed cell-death to avoid cancerous growth. Small changes in hormone concentrations lead to complex, cascading biochemical reactions that regulate these functions.

An endocrine disruptor is a chemical, or mixture of chemicals, that interferes with any aspect of hormone action. Suspected endocrine disrupting chemicals (EDCs) are commonly found in people, wildlife, and the environment. Over 800 chemicals have been identified as having endocrine disrupting properties. All of the 22 chemicals listed under the Stockholm Convention, a global treaty that restricts or bans some of the most hazardous chemicals used around the world, have endocrine disrupting properties.[20]

An irrefutable body of scientific evidence and international consensus exists about "the potential adverse effects of endocrine disruptors on human health and the environment [... and] the need to protect humans, and ecosystems and their constituent parts that are especially vulnerable."[21]

The adverse effects that are increasingly linked to exposure to chemicals with endocrine disrupting properties include: effects on reproduction, such as infertility and reduced sperm count and viability; breast, mammary, testicular, and prostate cancers; type 2 diabetes, obesity, and heart disease; neurobehavioral outcomes; and thyroid and immune system dysfunction.

There are several key features of endocrine disrupting chemicals that make exposure to any dose of an EDC unsafe, including:

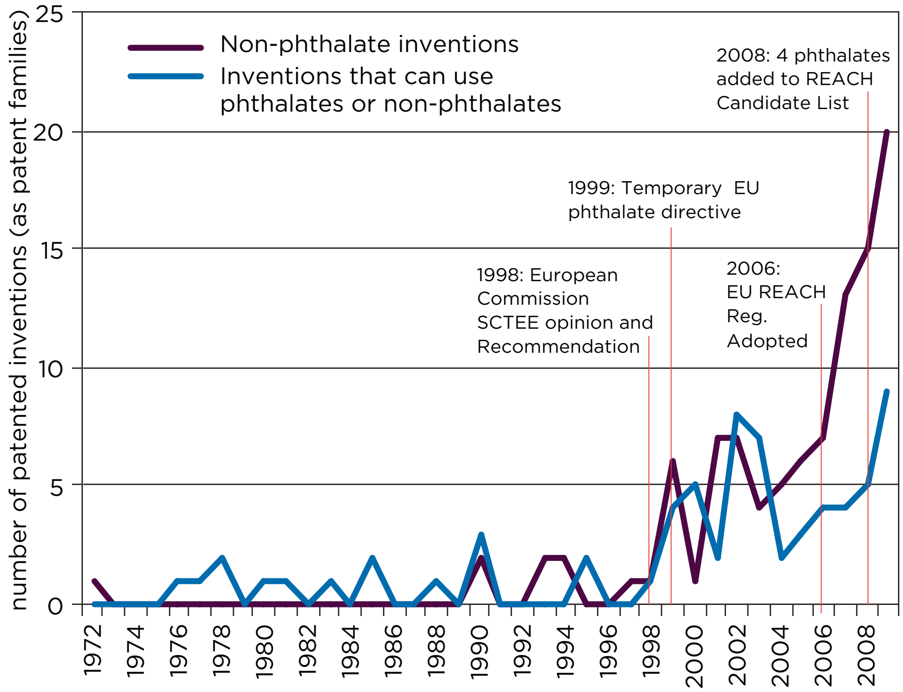
- **Low-dose effects:** Exposure to low doses of one or more EDCs may result in adverse effects that are not observed at higher doses.[22] In other words, a classic (linear) dose response curve of the risk accompanying exposure at varying levels does not apply to EDCs. As a result, conventional risk assessment methods, which extrapolate high-dose effects to predict low-dose effects, are inadequate to assess the effect of EDCs, and current methodologies cannot be used to derive safe doses of these chemicals.
- **Cocktail of chemicals:** Populations are regularly exposed to multiple EDCs. The effects of the individual chemicals in the "cocktail" of chemicals to which humans and wildlife are exposed may be additive, synergistic, or even antagonistic, such that exposure to multiple EDCs may have a combined effects not observed in examination of the hazards of an individual chemical.
- **Exposure during critical windows of development:** Exposure to EDCs during specific critical windows of a child's development can produce permanent adverse effects. Childhood exposure can occur pre- or post-natally through the presence of these chemicals in mother's blood or breast milk, food, or indoor environment.
- **Effects on Future Generations:** Studies of the progeny of women exposed to EDCs during their first trimester of pregnancy show reproductive abnormalities occurred 20 times more frequently in their male grandchildren. Daughters of the women also exhibited an increased incidence of breast cancer, vaginal, and cervical cancers, and reproductive abnormalities.[23] These effects illustrate the dangers of EDCs for future generations and the complexity of the challenge for epidemiology: the adverse effect(s) of exposure might not be observed until several decades after exposure and may not affect the health of the person initially exposed.
- **Ubiquity in the Environment:** Polar bears in the arctic, frogs and other forms of wildlife have all exhibited unusual hermaphroditic traits.[24] These observations in remote regions of the world illustrate the extent to which these hazardous chemicals persist and travel throughout the global environment through various media.

to the Member States of the European Union (EU), Canada, Japan, Iceland, Mexico, Norway, Argentina, Tunisia, and the United States are among the many countries that took measures to ban or restrict the use of certain phthalates. Four of these phthalates (BBP, DEHP, DBP, and DIBP) were added to the EU's REACH Candidate List, and subsequently the REACH Authorization List (see Box 4, below, and Box 6, page 11).[25] Through their inclusion on the Authorization List, all uses of these phthalates in the EU are required to cease by February 21, 2015, unless a use has been specifically authorized.[26] Certain Member States of the EU continue to pursue more stringent domestic measures than measures at the regional level.

There is evidence that these measures sparked the invention of alternatives to certain uses of phthalates. Publicly available patent records illustrate a surge of inventions (measured by "patent families") to eliminate exposure to phthalates (see Figure 2). There is a noticeable acceleration in the filing of patents, and thus the pace of invention, beginning around

FIGURE 2

Spike in Patented Inventions Free of Hazardous Phthalates



Exponential growth in the number of patented inventions for phthalate alternatives beginning in 1999, coinciding with the adoption of stricter rules (as captured by the number of patent families for "non-phthalate" and "phthalate free" inventions).

BOX 4

The EU's REACH Regulation

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) is the EU's comprehensive chemical regulation. Its purpose is to ensure a high level of protection of human health and the environment from chemicals manufactured, imported, marketed or used within the European Union, while enhancing competitiveness and innovation.[27] When adopted in 2006, REACH replaced dozens of existing EU chemical laws, including laws from the 1970s that presumed the safety of tens of thousands of chemicals already in commerce. This presumption of safety for existing chemicals in use by the 1970s is still in effect in the United States for industrial chemicals, but many countries around the world are moving towards REACH-like system.

Reversing the presumption of safety for existing chemicals, REACH is premised on a "no data, no market" policy. Chemicals manufactured in quantities greater than 1 ton per year (around 30,000 chemicals in all), must be registered with the European Chemical Agency (ECHA). To this end, the manufacturer and importer must report about the chemical's intrinsic properties. Under REACH's tiered system, chemicals manufactured in the highest quantities or those known to have hazardous properties require more tests and are to be registered earlier in the process.

Following Evaluation of the information provided, an EU Member State or ECHA may propose that a chemical be identified as a Substances of Very High Concern (SVHCs) and placed on the REACH "Candidate List." Subsequently, a chemical on the Candidate List may be recommended for Authorization by ECHA. If approved by the European Commission, the chemical is placed on the REACH Authorization List, in which case companies must request authorization for specified uses after a "Sunset Date." For more information about the Candidate List's impact on innovation, see Box 6, page 11.

Alternatively, a Member State or ECHA may propose a Restriction to limit or ban the manufacture, marketing or use of certain chemical that poses an unacceptable risk to human health and te environment.

TABLE 1

Timeline of Certain Phthalate Measures Adopted around the World

Year	Country or Region	Measure
1998	European Union	European Commission Scientific Committee on Toxicity, Ecotoxicity and Environment (SCTEE) opinion on phthalates
1998	European Union	European Commission Recommendation for Member States to adopt measures required to ensure a high level of child health protection in regard to phthalate-containing soft PVC childcare articles and toys
1998	Norway	Banned the production, distribution, import and export of toys and other products aimed at children aged under three and containing phthalate plasticizers
1999	United States	Voluntary ban on phthalates in teethers, rattles, and bottle nipples
1999	European Union	Temporary ban on six phthalates (DINP, DNOP, DEHP, DIDP, BBP, and DBP) above a certain concentration in toys and childcare products intended to be put in the mouth by children less than 3 years old
1999	Argentina	Temporary ban on six phthalates above a certain concentration in toys and childcare products intended to be put in the mouth by children less than 3 years old
2000	Tunisia	Banned the importation, selling and distribution of all PVC toys and childcare articles intended to be put in the mouth by children less than 3 years old containing any of six phthalates above a certain concentration
2001	Japan	Enacted an ordinance on: Phthalates in toys to be put in mouth by children up to six years; toys of DEHP-containing PVC resin intended for use by children up to six years; and DEHP in food utensils and vessels
2005	European Union	Permanent ban on six phthalates (DINP, DNOP, DEHP, DIDP, BBP, and DBP) above 0.1 % in toys and childcare products intended to be put in the mouth by children less than 3 years old
2006	European Union	REACH adopted
2008	European Union	BBP, DEHP, DBP, and DIBP added to REACH "candidate list"
2009	European Union	BBP, DEHP, DBP, and DIBP proposed for REACH "authorization list"
2009	United States	DEHP, DBP, BBP permanently banned above 0.1 % in children's toys and certain child care articles. Interim ban of DINP, DIDP, DnOP above 0.1 % in a children's toy that can be placed in a child's mouth, and child care articles. These six phthalates as well as DIBP and DnPP are subject to further investigation under an U.S. EPA "action plan."
2011	European Union	BBP, DEHP, DBP, and DIBP added to REACH "authorization list"
2015	European Union	Only authorized uses of BBP, DEHP, DBP, and DIBP will be allowed in the EU

1999, following the initial EU measures, and accelerating again in 2006, around the time REACH was adopted. These time points correlate with years in which Europe led the world in adopting measures to reduce the use of certain phthalates (see Table 1).

Considering the varying degree of research and development required before the filing of a patent, inventors likely foresaw the enactment of stricter laws and began research necessary for the patent application beforehand, and filed when new laws appeared imminent to maximize their time period of exclusivity under the patent.[28] Because these events took place long before compliance deadlines, companies were afforded the necessary lead-time to develop and possibly patent their technological inventions. For example, the EU's temporary directive in 1999 was preceeded by a Recommendation by the European Commission in July of 1998, which itself was preceded by an opinion of the European Commission's Scientific Committee on Toxicity, Ecotoxicity, and the Environment in April of 1998.[29]

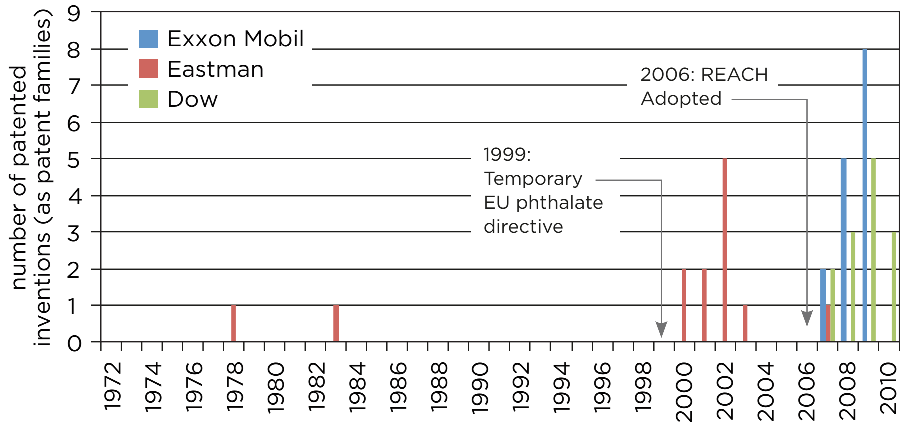
The correlation of increased invention in response to the prospect of stricter laws is consistent with other lessons of the past. For example, investigations of regulatory events surrounding lead, mercury, PCBs and vinyl chloride also confirm that informal regulatory procedures (before formalized rulemaking) drove companies to develop their technological responses.[30]

However, it was not until significantly strictly measures appeared likely (inclusion in the Authorization List under REACH), that major chemical manufacturers and others significantly increased their patenting of alternatives (see Figure 3, page 10). Nearly one-half of the patented inventions claiming an alternative to

. . . these measures sparked the invention of alternatives to certain uses of phthalates . . . . There is a noticeable acceleration in the filing of patents, and thus the pace of invention, beginning around 1999 and accelerating again in 2006. These time points correlate with years in which Europe led the world in adopting stricter measures to reduce the use of phthalates under Directives and REACH.

FIGURE 3

Stricter Laws Trigger Innovation by Major Chemical Manufacturers



Number of patented inventions by Eastman Chemical (formerly Kodak Eastman), Exxon Mobil and Dow Chemical from 1972–2010 for phthalate alternatives.

phthalates reference the health and environmental concerns surrounding this class of chemicals.

This surge in the invention of alternatives to phthalates began the same time as European laws limited the use of six widely used phthalates in toys and other children's products, a small percentage of global phthalate use. To some degree, both the number of phthalates and the number of products within the scope of laws around the world are increasing, and stand to increase further as the deadline for authorization of uses for certain phthalates approaches in the EU.[31] This trend towards stricter laws over the use of phthalates spurred the invention of phthalate alternatives beyond the miniscule share of the market occupied by toys and children's products.[32]

Exxon Mobil and Dow did not begin to aggressively patent alternatives to phthalates until after REACH was adopted in 2006.

The acceleration in the number of non-phthalate and phthalate-free patents illustrates how the prospect of progressively stricter rules against the use of hazardous chemicals can incentivize, or push, companies to develop alternatives. The number of patents filed throughout this period of progressively stricter rules for phthalates continues to grow, suggesting that companies continued to invent alternatives after new laws entered into force. For example, Exxon Mobil and Dow did not begin to aggressively patent alternatives to phthalates until after REACH was adopted in 2006 (see Figure 3). This illustrates how stricter laws can push innovators to develop alternatives. Eastman moved earlier than Exxon Mobil and Dow, but their strategy was to pursue inventions that could use either phthalate or non-phthalate chemicals. Exxon Mobil and Dow, however, appear to be pursuing an innovation strategy around inventions that are free of phthalates.

BOX 5

Patents and Measuring Innovation

Several different indicators are used to measure the pace of innovation. These include proxies such as the number of research publications, investment in research and development (R&D), number of scientists, and the number of patents. Each proxy has advantages and disadvantages.

Generally, a patent provides the right to prevent others from making, using, offering to sell or selling the invention patented for a limited time period. Unlike many other proxies, patent data is publicly available—a result of the bargain struck by governments, limiting competition in exchange for the inventor's knowledge. In return for a qualified right to exclude others from making, using, selling or offering to sell the patented invention for about 20 years, the public enjoys the possibility of using the inventor's knowledge after the patent expires, without any financial obligation to the inventor. To obtain a patent, inventors must meet minimum standards of "inventiveness," in other words novelty and utility, and may not claim more than one invention per patent. Thus, patents provide a relatively uniform standard unit of innovation.

Patents are not a perfect measurement of invention. The scope, value, and power of the ideas disclosed can vary widely from patent to patent. Also, many inventions are not patented, but rather kept as trade secrets. And the standards of patentability can vary to some degree across countries, although there has been considerable global harmonization recently. However, patents can serve as an indication of interest in a particular scientific area, such as alternatives to phthalates. Counting "patent families," rather than individual patents, avoids the problem of counting the same invention more than once because it has been patented in multiple countries.

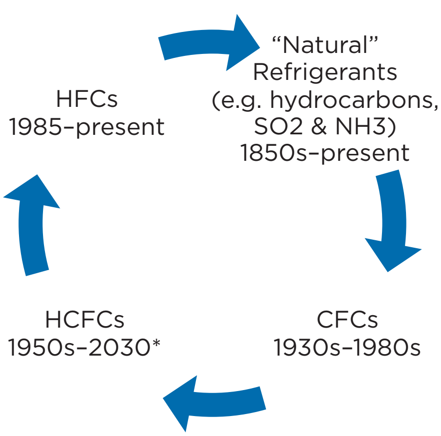
Stricter laws drive the invention of CFC Alternatives

Chlorofluorocarbons (CFCs) displaced ammonia, sulfur dioxide, carbon dioxide and other "natural" refrigerants in the 1930s. Unlike these refrigerants, CFCs were adopted because they offered a safer alternative in terms of their toxicity, flammability, and/or energy efficiency.[33] Unfortunately, it was not until many decades later that these chemicals were widely acknowledged to be ozone depleting substances.[34] Other uses for CFCs included foam production (e.g. Styrofoam™), aerosol products, and as solvents for cleaning products with delicate components such as electronics.

Chemical companies were alert to the human health and environmental consequences of CFC emissions as early as 1972. Following a 1972 conference, DuPont and other CFC manufacturers formed a consortium coordinated by what is now the American Chemistry Council (ACC), a U.S. trade association for chemical manufacturers. When ozone depletion resulting from CFC emissions began to gain substantial mainstream attention in 1974, members of the consortium defended the continued use of CFCs, and called for additional scientific evidence, insisting their chemicals were safe until proven otherwise. It was also argued that health and wealth would decline in a world without CFC products.[35]

FIGURE 4

Innovation Cycle of Refrigerants



Innovation of various chemical refrigerants over the 20th and 21st centuries. Dates are approximations based on major usage and expected reductions under national and international agreements.[36]

BOX 6

The REACH Candidate List: A Key Driver of Innovation

According to the European Commission's interim evaluation of the impact of REACH on innovation in Europe (REACH Innovation Report), "the Candidate List is a, if not *the*, major driver for change at present."[37]

Among other findings, the REACH Authorization process was found to have a similar effect to the Candidate List, but for a smaller number of firms.[38] Registration of chemicals under REACH is projected to have an impact on substitution as some chemicals may not be registered or produced at lower volumes, reducing supply—a "trigger" for innovation.[39] Safety Data Sheets (SDSs), enabling communication of information about hazardous chemicals along the supply chain, made the strongest contribution to stimulating the conception of new products.[40]

The REACH Candidate List identifies a chemical as being a Substance of Very High Concern (SVHC) based on information about its intrinsic properties, such as: whether it causes cancer, creates genetic mutations, negatively affects reproduction (CMRs); persists in the environment, accumulates in living organisms, and/or are toxic (PBTs or vPvBs); or rises to an equivalent level of concern, such as endocrine disruptors (see Box 2, page 5). Criteria for identifying chemicals of concern based on their endocrine disrupting properties under EU law are currently under negotiation.[41]

The REACH Innovation Report suggests that the Candidate List is driving innovation through substitution, reformulation, and withdrawal.[42] The most common response of firms was reformulation, followed by withdrawal, substitution, and launching of initiatives to develop new chemicals.[43] The European Commission's Report also found that uncertainty regarding substances that will appear on the Candidate List in the future is driving retailers and downstream users to request greater levels of SVHC absence than required with under REACH.[44] Both of these observations illustrate that the Candidate List is driving businesses to innovate away from chemicals of concern.

As more information is provided about the intrinsic hazards of chemicals within the scope of REACH, the Candidate List stands to continue to drive innovation in the chemical industry.[45] With broad criteria for indentifying endocrine disrupting chemicals and information about endocrine disrupting properties of chemicals, it stands to reason that the Candidate List will further drive innovation.

Simultaneously, research and development into alternatives was well-underway, with several alternatives identified. During debate over stricter measures on CFCs and other ozone depleting substances, representatives of DuPont and other CFC manufacturers stated that they had identified technically viable alternatives to CFCs between 1975 and 1980, but could not introduce these alternatives because, by their estimates, the alternatives would not be economically viable (see Chapter 4).[46] Later, these manufacturers acknowledged that it was the lack of legally-enforceable standards that prevented the entry of safer alternatives.[47]

The United States, Canada, Sweden, and Norway announced plans to ban non-essential aerosol products in 1976, aided in part by slumping sales of CFC-containing products due to consumer concern. These laws at the national level spurred changes in the industry, most notably in the United States. Changes in the U.S. industry in turn positioned the United States to push more actively for international laws over ozone depleting substances, given its own competitive advantage.[48]

In 1987 countries around the world agreed on a timeline for the global phase out of CFCs under the Montreal Protocol. A patent search by the World Intellectual Property Organization showed that various chemical manufacturers and other diversified businesses in both Japan and the United States patented a variety of processes, including the process for the manufacture of one of the most widely used alternatives to CFCs, hydrofluorocarbon (HFC)-134a, in 1987 and 1988.[49]

Thus, the prospect of stricter laws at the national and global level spurred inventors to research alternatives to CFCs and hydrochlorofluorocarbons (HCFCs), leading to the development of both HFCs and inventions for the safer use of "natural" refrigerants (used in the 1930s before CFCs) as alternatives to CFC refrigerants. HFCs prevailed over ammonia, carbon dioxide and other "natural" refrigerants due to the cost advantages. However, while HFCs are not ozone depleting substances, they are potent greenhouse gasses. Aided by stricter laws in Europe that phased out HFCs in new cars after 2011, and public campaigns to use hydrocarbons in domestic refrigerators, considerable research and development continued around the use of natural refrigerants. Incremental inventions enabled these "natural" refrigerants to overcome properties deemed undesirable almost a century ago (see Table 2). With the continued development of natural refrigerants, hydrocarbon domestic refrigerators are now economically viable and commonly available in Europe and Asia, with both environmentalists and manufacturers alike advocating for the U.S. to adopt them as well.[51] In addition, suppliers of equipment using ammonia rather than HCFCs recaptured market share in cold storage and food freezing.[52]

The prospect of progressively stricter laws over CFCs and other ozone depleting substances sparked the continuous invention of alternatives, including improved methods of using natural refrigerants, making the chemicals once displaced by CFCs a viable alternative to ozone-depleting substances and greenhouse gasses. Together, the experiences of both phthalates and CFCs illustrate how the systematic introduction of progressively stricter rules at the global and regional levels spurred the continuous invention of safer chemicals, averting the serious consequences of inaction and disproving the estimated cost of action.

TABLE 2

Intrinsic Properties of Various Chemical Refrigerants

Chemical	Ozone depleting potential (relative to CFC-11)	Global warming potential (relative to CO_2)	Other hazardous properties
Ammonia*	0	< 1	Highly toxic (but odor enables evacuation), slightly flammable
Carbon Dioxide*	0	1	Toxic at high doses
CFC-11	1	4,600	
CFC-12	0.820	10,600	
HCFC-22	0.034	1700	
HFC-134a	0	1300	
Hydrocarbons*	0	~20	Flammable

* "Natural" refrigerants[50]

CHAPTER 3

Chemical Laws Can Pull Safer Inventions into the Market—But Not All Alternatives Are Safer

Innovation hinges on the adoption of an invention. As illustrated above, chemical laws can accelerate the invention of alternatives to hazardous chemicals. To replace widely used hazardous chemicals, inventors created new chemicals and processes, developed new uses for existing chemicals, and found alternative approaches. The spike in invention to eliminate certain phthalates shows that environmental laws can be a critical element—a driver—in accelerating invention in the chemical industry.

Chemical laws can also pull inventions into the market, thereby turning invention into innovation. The above examples of CFCs and phthalates illustrate this. Some of the alternatives that were used for certain phthalates and CFCs existed well-before the prospect of stricter laws was on the horizon. Until the prospect of enacting stricter restrictions on the use these entrenched and hazardous chemicals, these alternatives were sidelined, with far less opportunity for adoption in the market and further development through experience gained from their successes and shortcomings.

However, some of the replacements for chemicals of concern have been very unsatisfying. History is replete with examples of regrettable substitution, where years of concerted effort is undertaken to restrict or phase-out an individual chemical of concern, only to see the chemical replaced with a different chemical of concern.[54] This unsatisfying transition has undermined the confidence of the public and businesses in the ability of innovation alone to ensure meaningful progress towards safer alternatives. Below, a cross-section of examples of substitution is presented, ranging from clearly regrettable substitutes, to the entry of alternatives that raise questions, and, finally, to more promising examples.

"For quite some time I have been confronted with problems from the plasticizers in vinyl for aerospace applications and I have long since come to the conclusion that vinyl should not be permitted in any phase of aerospace usage…substitute polymers for the vinyl are readily available and in many cases they have far superior physical properties at a small sacrifice in immediate cost."

— April 26, 1971 (A letter to *Chemical and Engineering News* from Frederick G. Gross of the NASA Materials Engineering Branch)[53]

Regrettable substitution

Over the last several decades, demand for chemical flame-retardants has accelerated. Production increased from just over 500 million pounds in 1983, to 3.4 billion pounds in 2009, and is projected to jump another 30 percent to 4.4 billion pounds by 2014.[55] The transition away from toxic flame retardants provides one example for regrettable substitution.

Polychlorinated biphenyls (PCBs) and polybrominated biphenyls (PBBs) were widely used as flame-retardants until the 1970s, when health and environmental concerns began to surface. When PCBs and PBBs were banned as flame retardants, polybrominated diphenyl ethers (PBDEs) took their place in the market as flame-retardants. Under U.S. and European laws at the time, PBDEs were considered "existing" chemicals, meaning no evidence of safety was required for these chemicals to remain on the market when they were introduced. Production and use increased rapidly for PBDEs over the next several decades as new markets for them emerged, or were created, including furniture foam, electronics, textiles, and baby products.

PBDEs are a regrettable substitute for PCBs as flame retardants. Overwhelming evidence has emerged about the hazards of PBDEs, including their endocrine disrupting properties.[56] Not only do these chemicals exhibit toxicity at both high and low-doses, but they persist in the environment rather than breaking down into safer constituents, accumulate in living organisms, and travel long-distances through wind, water, animals in which they accumulated, and products traded internationally. As evidence of the dangers of PBDEs grew overwhelming, many countries around the world began to phase out certain PBDEs, creating the possibility for the entry of safer alternatives. In other countries, manufacturers of PBDEs agreed to voluntarily discontinue the production and sale of these chemicals. Two types of PBDEs were banned in 2009 under the Stockholm Convention, a global treaty that applies to some of the world's most hazardous chemicals. PBDEs are one example of regrettable substitution among a cluster of toxic flame retardants.

Unfortunately, one of the replacements for certain PBDEs is yet another episode of regrettable substitution. Firemaster 550™, a mixture of several chemicals, was approved for use by U.S. EPA in 2003 under the U.S. Toxic Substances Control Act's (TSCA's) provisions for the approval of new chemicals.[57] Because of the limited power for regulators to demand sufficient proof of safety before a new chemical is produced for use, the U.S. Environmental Protection Agency (U.S. EPA) could only use the scant information provided by the manufacturer (Chemtura) and computer models to predict the chemical mixture's toxicity. According to an U.S. EPA official, "[w]e didn't think [Firemaster 550™] would bioaccumulate, but it turns out that prediction isn't borne out by reality."[58]

Regulators in the U.S. approved Firemaster 550™ for use, even though it had suspicions, including the structural similarity of a chemical ingredient of Firemaster 550™ to DEHP, a phthalate restricted from certain uses due to evidence that it is a reproductive toxin (see Figure 5). U.S. authorities asked the manufacturer, Chemtura, to provide additional studies. Chemtura provided two of its own studies, five years later, which showed adverse effects at high-doses, such as skeletal malformations and low-birth weight. The company argued that these were inconclusive.

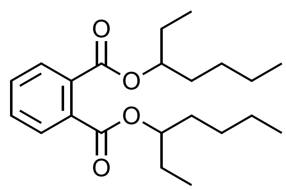
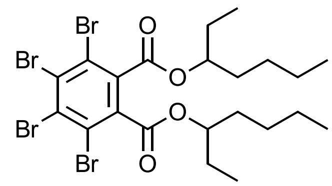
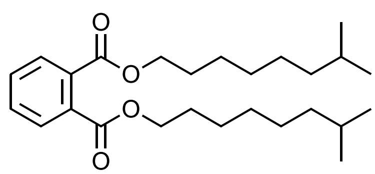
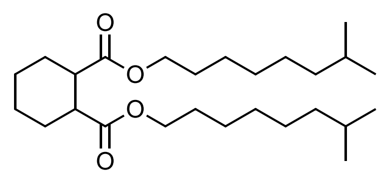
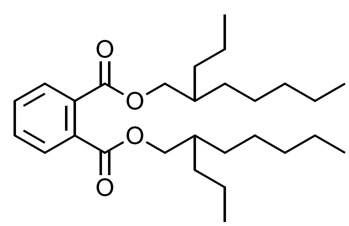
Although advertised as a "green" replacement to PBDEs,[59] evidence continues to emerge that one or more ingredients of Firemaster 550™ are released from products containing the mixture, could be toxic, accumulate in wildlife, travel long-distances through the environment, and may have adverse effects at low-doses. Like PBDEs and structurally similar phthalates, recent studies indicate that some of Firemaster 550s ingredients have endocrine disrupting properties.[60] As one group of researchers reported:

> This exploratory study reveals, for the first time, the potential for perinatal FM [(Firemaster)] 550 exposure to have adverse effects indicative of endocrine disruption, at levels much lower than the [No Observed Adverse Effect Level (NOAEL)] reported by the manufacturer. These findings are significant because FM 550 appears to be one of most commonly used replacements for PBDEs in foam and is prevalent in house dust.[61]

However, Firemaster 550™ remains in use.

FIGURE 5

Risky Transition to Structurally Similar Chemicals as Substitutes for Hazardous Chemicals

Hazardous Chemicals with Use Restricted	Structurally similar substitutes for hazardous chemicals, increasingly questioned regarding their own safety
A DEHP: Use restricted (general purpose phthalate) 	**B** Firemaster 550™ ingredient TBPH: In use as an alternative to PBDE flame retardants 
C DINP: Use restricted (general purpose phthalate) 	**D** Hexamoll® DINCH: In use as alternative to DINP and other suspect phthalates 
	E DPHP: In use as alternative to DEHP and other suspect phthalates 

Structurally similar alternatives that have been used as substitutes for hazardous chemicals: (A) DEHP, a hazardous phthalate with restricted use in many countries; (B) TBPH, an ingredient of Firemaster 550™, a substitute for toxic flame retardant chemicals; (C) DINP, a hazardous phthalate with restricted use in many countries; (D) DINCH, a substitute for hazardous phthalates DEHP and DINP; and (E) DPHP, another substitute for DEHP and other hazardous phthalates. "Use restricted" does not mean that it is restricted from all products or in all countries.

Questionable Substitution

The inventions introduced as alternatives to the handful of phthalates singled out by the law illustrate the potential for regrettable substitution. A chemical's form and function are closely linked. The form of a molecule determines both its function in a polymer, as well as its function in biochemical pathways, which may lead to adverse effects. Although slight changes to a chemical's structure can make a difference in terms of its physical or biological functionality, there is a significant likelihood that the substitute chemical will not be devoid of intrinsic hazardous properties. While these slight structural modifications to hazardous chemicals can minimize the redesign of products and processes, chemical-by-chemical approaches to hazardous chemicals can delay a meaningful transition to safer alternatives.

The substitution of certain phthalates of concern is an example of the substitution of structurally similar chemical alternatives. These structurally similar chemicals include both non-phthalates, such as BASF's Hexamoll® DINCH (DINCH), as well as different phthalates, such as DPHP (see Figure 5). Given the similarity in chemical form and corresponding potential for similarity in biological function, heightened attention is warranted about the potential for regrettable substitution in these cases.

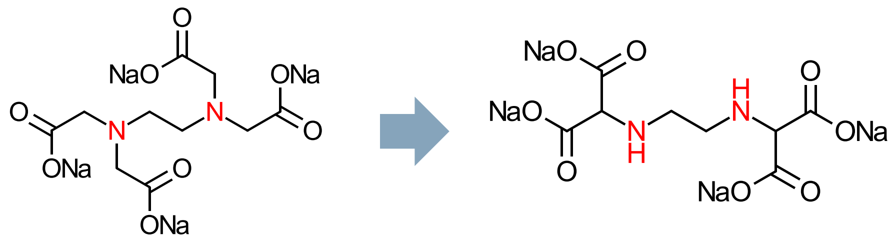
DINCH was developed by chemical manufacturer BASF Corporation around 2003 for use as a PVC plasticizer and, specifically, to replace DEHP and DINP in products such as food contact applications, childcare articles, and children's toys.[62] Other targeted application areas include medical articles and shoes, as well as non-PVC applications such as adhesives, cosmetics, artificial leather, textile coatings, and erasers. DINCH has been shown to migrate from PVC food contact surfaces into food, particularly into high fat content food such as oils and cheeses.[63] This alternative is an attractive substitute to phthalate manufacturers because DINCH is produced through the conversion (hydrolysis) of DINP to DINCH.[64]

According to staff at U.S. Consumer Products Safety Commission (CPSC):

> No published studies of DINCH were found. The only information located regarding the health effects of DINCH was found in the [Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)] (2007) report, which contained summaries of unreferenced and unpublished studies submitted by BASF Corporation, and in an abstract/summary of one of these studies submitted by BASF Corporation to EPA under the Toxic Substances Control Act (TSCA) and identified in the search of the [TSCA] database [of testing results].[65]

FIGURE 6

Chemicals Can Be Designed to Be Safer



EDTA　　EDDS

The conversion of EDTA's tertiary nitrogen atom to a secondary nitrogen atom (EDDS) enables EDDS to degrade faster and thus mobilize less toxic metals in the environment, while also out-performing the more persistent EDTA by other standards of performance as well.

A structural analog to the phthalate DINP (see Figure 5), DINCH is said to be a suitable direct substitute due to its similar plasticizing performance. Given the structural similarity to phthalates, in particular DINP, a heightened level of scrutiny appears prudent. However, there is a lack of available exposure and toxicological data on DINCH.[66] Among those available, short-term, sub-chronic, chronic, and two-generation reproductive oral studies in rats did however show effects of DINCH on the liver, urinary tract and, in particular, thyroid.[67] Of particular concern, given the endocrine disrupting properties of structurally similar phthalates to DINCH, is that studies were insufficient with respect to information on dose-response relationships.[68]

The CSPC analysis concludes that "[w]hile DINCH is entering the market as a component of consumer products such as children's articles, the insufficiency of these study summaries preclude independent evaluation of the results and reliable identification of adverse effect levels."[69] In 2012, several years after its approval, U.S. EPA requested that DINCH be added to its list of "Priority Testing Substances" for additional testing data.[70] Health and Safety Data Reporting (HaSDR) rules under TSCA require importers, manufacturers and processors of Priority Testing List chemicals to submit unpublished Health and Safety studies within 90 days of the rule's date of publication in the U.S. Federal Register.

The tendency to transition to structurally similar alternatives to minimize the disruption to existing production processes and business models highlights the need to produce and review sufficient information before alternatives are adopted as substitutes for hazardous chemicals.

More Promising Examples of Substitution

Chemists have invented ways to design chemicals that are inherently safer. An older example is the ability to design chemicals so that they do not persist as long in the environment.[71] One such technique is the use of secondary nitrogen atoms instead of tertiary nitrogen atoms to enhance biodegradability, as demonstrated with the use of ethylenediamine-N,N'-disuccinic acid (EDDS) instead of ethylenediaminetetraacetic acid (EDTA) as a complexing agent (see Figure 6). Complexing agents like EDTA can be used to improve cleaning efficiency by sequestering metals in water-based solutions, but also raise concerns about their ability to mobilize toxic metals in the environment.[72] EDTA has been phased-out for certain application in some countries and regions.[73] EDDS is far more biodegradable than EDTA, and also performs better as a complexing agent in some applications.

More recently, scientists have created a cost-effective system that they believe will help industry more effectively identify—and avoid—chemicals with endocrine disrupting properties.[74] To ensure that the protocol remains current as the scientific understanding of endocrine disruption continues to advance, the inventors established a plan for incorporating new assays into the protocol.

With the increasing stringency of measures on the use of certain phthalates, including the scheduled phase out of four phthalates (DEHP, DBP, BBP and DIBP) from certain products in the EU by 21 Feb. 2015, alternatives to certain phthalates are increasingly being demonstrated as viable and adopted. While DINCH and phthalate-based alternatives raise questions, other alternatives to phthalates show more promise.

For example, a castor oil-based alternative to phthalate plasticizers for PVC (Soft-n-Safe™) was invented through experiments with different types of raw materials as feedstocks. It has been approved for use in food contact surfaces, vinyl flooring and wallpaper, toys, medical devices, inks, textile dyes, and other applications.[75] This direct substitute does not exhibit many of the intrinsic hazards of phthalates and other plasticizers. Notably, and unlike the phthalates they replace, studies show no evidence of endocrine disruption or other adverse effects for this alternative.[76]

In order to increase the likelihood that safer alternatives will be pulled into the market, chemical laws need to clearly identify hazardous properties that are not acceptable in society, generate information about these properties in all chemicals, and require their substitution with safer alternatives in a systematic way.

In the effort to remove phthalates from products, other companies have removed a principle reason phthalates are used in the first place—PVC. For example, office products retailer Staples removed PVC from its packaging materials. Downstream users are also removing phthalates by removing the PVC. Of particular concern is the use of phthalate-containing PVC for blood bags and other infusion/transfusion sets, which can subject very young children to hazardous levels of the phthalate DEHP during critical windows of development. As a result of recent measures for certain phthalates, medical suppliers that provide phthalate-free alternatives to PVC medical devices are experiencing a boom in both demand and growth.[77]

Innovators have also found safer alternatives to treating furniture foam with toxic chemicals to prevent furniture fires. For example, specially designed upholstery can resists smoldering cigarettes, preventing underlying foam from igniting. In addition, researchers developed nontoxic fire-resistant barriers for couches, using an earlier concept for mattresses. Both of these alternatives are far more effective at slowing fire than adding flame retardants to foam, which in fact does not slow the fire by any significant degree according to several tests by government agencies and independent laboratories.[78]

Specially designed upholstery and fire-resistant barriers are shown to be more effective at slowing fires than the addition of toxic flame-retardant chemicals to furniture foam, which contaminate indoor and outdoor environments and are linked to adverse health effects.

The above examples illustrate how invention has been sparked by laws to reduce or eliminate hazardous chemicals. First-movers may have a considerable advantage over competitors as demand and requirements for safer products increase.

Legal controls cleared the way for the adoption of alternatives, pulling newly developed or pre-existing solutions to occupy the space vacated by certain hazardous chemicals. In order to increase the likelihood that safer alternatives will be pulled into the market, the law needs to clearly identify hazardous properties that are not acceptable in society and require their substitution with safer alternatives (including non-chemical alternatives) in a systematic way. For example, the EU's REACH authorization procedure gives a clear signal to industry that chemicals that are carcinogens, mutagens, or toxic to reproduction, or those that exhibit persistence and bioaccumulation, need to be substituted with safer alternatives. This provides clear direction to chemical manufacturers and downstream users of chemicals that they must innovate away from chemicals with these properties.

The availability of information about chemical hazards and the prospect of regulatory action accelerate research towards safer solutions, whether it is through the invention of new chemicals, new applications of existing chemicals, new materials, or new processes.[79] But, critically, stricter requirements that chemical manufacturers generate information about intrinsic hazards and exposures can drive innovation in a safer direction. Without information about the full scope of intrinsic hazards of all chemicals, downstream businesses are highly vulnerable to investing in the substitution of one hazardous chemical with a different hazardous chemical. Some might say they risk jumping from the frying pan into the fire.

BOX 7

Green Chemistry

It is commonly accepted that a chemical's risk is a function of intrinsic hazards and exposure. Most efforts at reducing risk to human health from chemicals have focused on reducing the probability and magnitude of exposures. The track record for predictions of exposure is abysmal.[80] Green chemistry deals with risk by seeking to eliminate intrinsic hazards rather than by controlling exposure.[81]

Over the past several years, the concept of green chemistry has increasingly been embraced by a range of businesses that produce and use chemicals.[82] This promising approach to chemical synthesis and manufacture aims to design chemicals that meet the functional demands of the market, but are also inherently safer and more resource- and-energy-efficient. In other words, green chemistry is the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances. Fewer hazardous substances mean less hazardous waste and a healthier environment. These changes can create safer jobs, produce healthier lives, and reduce economic costs to businesses from the use or generation of toxic chemicals.[83]

The twelve principles of green chemistry[84] are:

1. **Design safer chemicals and products:** Design chemical products to be fully effective, yet have little or no toxicity.
2. **Prevent waste:** Design chemical syntheses to prevent waste, leaving no waste to treat or clean up.
3. **Design less hazardous chemical syntheses:** Design the synthesis of a desired chemical such that only substances with little or no toxicity to humans and the environment are used.
4. **Use renewable feedstocks:** Use raw materials and feedstocks that are renewable rather than depleting. Renewable feedstocks are often made from agricultural products or are the wastes of other processes; depleting feedstocks are made from fossil fuels (petroleum, natural gas, or coal) or the mining of metals and minerals.
5. **Design chemicals and products to degrade after use:** Design chemical products to break down to innocuous substances after use so that they do not accumulate in the environment.
6. **Maximize atom economy:** Design syntheses so that the final product contains the maximum proportion of the starting materials. There should be few, if any, wasted atoms.
7. **Increase energy efficiency:** Run chemical reactions at ambient or room temperature and pressure whenever possible.
8. **Use catalysts, not stoichiometric reagents:** Minimize waste by using catalytic reactions. Catalysts are used in small amounts and can carry out a single reaction many times. They are preferable to stoichiometric reagents, which are used in excess and work only once.
9. **Avoid chemical derivatives:** Avoid using blocking or protecting groups or any temporary modifications if possible during synthesis. Derivatives use additional reagents and generate waste.
10. **Use safer solvents and reaction conditions:** Avoid using solvents, separation agents, or other auxiliary chemicals. If these chemicals are necessary, use less harmful or hazardous chemicals.
11. **Analyze in real time to prevent pollution:** Include real-time monitoring and control during chemical synthesis to minimize or eliminate the formation of byproducts.
12. **Minimize the potential for accidents:** Design chemicals and their forms (solid, liquid, or gas) to minimize the potential for chemical accidents including explosions, fires, and releases to the environment.

Venture capital and private equity investors are increasingly interested in companies inventing and developing alternatives to chemicals of concern. Investors see green chemistry as one of the most promising investments in looking towards 2015.[85] Analysts reported continued growth in investments to green chemistry firms, rising to 30 deals averaging around $20 million each in 2011.[86]

A 2011 assessment of green chemistry's market potential estimated it could soar from an estimated US$ 2.8 billion in 2011 to US$ 98 billion by 2020.[87] To the extent that safer substitutes displace more hazardous substances in the market, this represents a positive step in the right direction. Yet, even at this rapid pace, green chemistry would amount to a mere 1.5 percent of the 2020 market;[88] a positive contribution, but not a solution.

CHAPTER 4

Stricter Chemical Laws Can Enable Safer Alternatives to Penetrate Barriers to Entry

The ability of chemical laws to pull inventions into the market is a crucial aspect of the potential power of chemicals policies to spur innovation toward safer alternatives. Businesses may argue that environmental laws follow the invention of alternatives to hazardous chemicals, and thus is not a driver of innovation (see Figures 1 and 2). But, it is the prospect of stricter measures that often drives the research and development of new ideas, and later enables the entry of these ideas into the market.[89]

Part of this ability comes from the power of the law to enable new ideas, safer alternatives in this case, to overcome barriers to entry. Even if a safer alternative to a chemical of concern is invented and available for adoption, there are many factors that present barriers to its entry into the market. One factor is the substantial economies of scale for existing chemicals. Second, the continued externalization of costs by the chemical industry makes it difficult for safer alternatives to compete on a level playing field. A third factor is an inability of businesses, consumers, and regulators to access information about the hazards of chemicals and products containing hazardous chemicals. These three factors are discussed below.

Stricter laws enable safer alternatives to overcome economies of scale

After years of insufficient action to displace hazardous chemicals, many chemicals of concern on the market today enjoy substantial economies of scale relative to newer alternatives. These economies of scale result not only from the economies inherent in higher production volumes, but also from long periods in which innovations could occur around their production and use, with resulting increases in efficiencies and demand. The discovery of new uses, increasing production volumes and the development of more efficient processes for chemical synthesis enable existing chemicals to become more and more entrenched in products and processes. For example, methyl bromide, an ozone depleting substance being phased-out under the Montreal Protocol, was invented in the early 1900s and initially used as a fire extinguisher, but did not grow into one of the most widely used pesticides until the 1980s.

Projections for a relatively small market segment for green chemistry (see Box 7), together with the estimated 50% increase in the chemical industry's output from 2010–2020, suggests that the majority of the expansion of chemical production and use will be from the continued use of the current mix of chemicals in commerce.[90] This, together with projection for the continued expansion of the chemical industry in the coming years, suggests that questionable chemicals are poised to enjoy additional economies of scale. It stands to reason that as long as the existing product mix is deemed acceptable under law, green chemistry will face difficulty breaking into a market dominated by large companies with sunk investments in the status quo.

Methyl bromide, CFCs, and phthalates provide examples of the economies of scale enjoyed by incumbent chemicals and the ability of stricter laws to enable alternatives to overcome this barrier to entry.

Methyl bromide offers one example of how stricter laws can enable alternatives to overcome economies of scale. Restricting the production of methyl bromide caused the price of methyl bromide to increase 400 percent from 1995–2001, making alternatives more cost-competitive.[91] This price increase enabled the further development and demonstration of alternatives to methyl bromide. For example, the U.S. EPA notes that, with additional testing, steam sterilization could become a technically and economically feasible "non-chemical" alternative to methyl bromide.[92]

For years DuPont and other manufacturers argued that alternatives to CFCs were identified but not economically viable, thanks in large part to the economies of scale enjoyed by CFCs.[93] Their analyses suggested higher costs to consumers, and lower profits to chemical manufacturers. DuPont claimed that it ended its US$ 15 million research program for alternatives in 1980 because company leaders believed the options developed would be uneconomical due to the investment necessary to modify changes production facilities, and the time required for development and marketing.[94] Cost estimates for HFCs by industry were three to ten times the cost of CFCs.[95] These costs projections were not borne out by reality.[96] Moreover, there is consensus among stakeholders that the costs of preventing ozone depletion are far less than the consequences of inaction.[97]

DuPont later acknowledged that the lack of legally enforceable standards around the world prevented industry from overcoming the economies of scale enjoyed by CFCs and other ozone depleting substances.

Neither the marketplace nor regulatory policy, however, has provided the needed incentives to make these equipment changes or to support commercialization of the other potential substitutes. If the necessary incentives were provided, we believe alternatives could be introduced in volume in a time frame of roughly five years.[98]

DuPont

Another example is provided by alternatives to DEHP, DINP and other phthalates subject to stricter laws. As mentioned above, many of the alternatives to phthalates singled out by relevant laws have been known for decades.[99] These alternatives were undeveloped and underutilized in large part because of the economies of scale enjoyed by incumbent high-production volume chemicals. As certain phthalates became subject to stricter laws, companies with underdeveloped alternatives received substantial funding to develop and demonstrate their technologies as viable alternatives, to facilitate adoption by a broader market segment.[100]

Industry often points to the lack of manufacturing capacity as a contributing factor in the inability of alternatives to displace existing chemicals of concern. This argument was raised during debates over CFCs, phthalates, and methyl bromide. During an assessment process for phthalate alternatives begun in the United States in 2011, a chemist with 30 years' experience at Exxon Mobil claimed that "[m]anufacturing capacity does not exist globally to enable alternatives to replace phthalates."[101] The chemist opined that global production capacity for general plasticizers (DEHP, DINP, DIDP, and DPHP) was over 10 billion pounds, whereas potential alternatives to general plasticizers totaled less than 0.5 billion pounds. Non-phthalate plasticizer products are, according to the former industry scientist, "[u]navailable in sufficient quantities or at competitive pricing to supply a large portion of flexible PVC market."[102]

However, lower manufacturing capacity and relatively higher prices will always be the case for potential alternatives to chemicals entrenched in various uses, such as general purpose phthalates, when they are first introduced. This does not mean that manufacturing facilities for the production and use of a chemical of concern cannot be converted over time, or that prices will not fall as economies of scale develop as production and use of the safer alternative increases. For example, Eastman Chemical obtained facilities to increase its capacity to manufacture non-phthalate plasticizers.[103] Legal measures also have a role to play in creating incentives for necessary changes in production facilities, as exemplified by controls over ozone depleting substances.

CFCs, certain phthalates, and methyl bromide are just a few examples of hazardous chemicals that, through innovation, found new applications beyond the purpose for which they were developed. As new uses and improved production processes developed, these chemicals enjoyed increasing economies of scale. These chemicals ranked among the highest in terms of volume of production before regulators enacted measures to reduce their production and use. Until stricter measures were put in place, alternatives to these chemicals were unable to capture significant market share or attract substantial resources for further development. So long as hazardous chemicals remain available for use, there remains the likelihood that new uses for these chemicals will develop, along with the increased risk of exposures and the challenge of removing a more widely used hazardous chemical in favor of a safer alternative.

Overcoming the inertia of entrenched toxic chemicals requires the power of the government. Safer alternatives need conditions that enable them to overcome economies of scale that are enjoyed by many chemicals of concern. The ability of regulators to restrict or remove chemicals of concern, and promote the development of safer alternatives, is a powerful tool to help pull inventions into the market, enabling economies of scale to develop around safer alternatives rather than incumbent chemicals of concern. This power can displace entrenched chemicals, creating the opportunity for safer chemicals and other innovative solutions to enter in their place.

Stricter laws reduce externalized costs, enabling the entry of safer alternatives

Externalities are costs or benefits arising from an economic activity that affect somebody other than the people engaged in the economic activity and are not reflected fully in prices.[104] Pollution is an example of a negative eternality, where the public rather than the polluter bears the cost of pollution. Recognizing the inefficiencies of externalized costs, the global community has recognized the importance of the "polluter pays principle," articulating that:

> [n]ational authorities should endeavor to promote the internalization of environmental costs and the use of economic instruments, taking into account the approach that the polluter should, in principle, bear the cost of pollution, with due regard to the public interest and without distorting international trade and investment.[105]

Over the last two decades, the global community has reaffirmed the polluter pays principle, emphasizing its importance in the 2002 World Summit on Sustainable Development,[106] the Stockholm Convention on Persistent Organic Pollutants and the Global Plan of Action of the Strategic Approach to International Chemicals Management (SAICM).[107] Today, however, the large costs of chemical exposure are borne overwhelmingly by governments and the public, not by polluters.

Recent analyses by the UN Environment Program (UNEP) highlight the cost of inaction for the sound management of chemicals on human health and the environment, with large burdens falling on individuals and government budgets. These reports conclude that "the vast majority of human health costs of chemical production, consumption and disposal are not borne by chemical producers, or shared down the value-chain. Uncompensated harm to human health and the environment are market failures that need to be corrected."[108]

In a recent analysis by World Health Organization (WHO) experts found that the global burden of disease from industrial and agricultural chemicals (for which data was available) amounts to 2.0% of total deaths and 1.7% of the total burden of disease worldwide.[109] When including air pollution and arsenic in drinking-water, the global burden of disease amounts to 8.3% of total deaths and 5.7% of the total burden of disease. Noting the limited number of chemicals included in the study and insufficiency of large-scale exposure data, the authors note that the estimates in the study "undoubtedly underestimate" the real burden attributable to chemicals.[110]

Exposure to endocrine disrupting chemicals is linked to a host of adverse effects, such as: breast, testicular, and prostate and other cancers; effects on reproduction, including infertility and reduced semen quality and quantity; type 2 diabetes, obesity, and heart disease; developmental neurotoxicity; and thyroid and immune system dysfunction.[111]

These effects impose substantial costs on individuals, governments, and society at large.

For example, lost years of life and productivity caused by cancer represent the single largest drain on the global economy compared to other causes of death.[112] Over 200 chemicals are classified as known or probable carcinogens, with many of these carcinogens remaining nearly ubiquitous in environments where people are easily exposed.[113] The total economic impact of cancer at the global level was estimated at US$ 895 billion in 2008, or 1.5 % of global GDP.[114]

Estimates of the environmentally induced portion of the costs of diabetes, thyroid disorders, IQ loss, and Parkinson's disease —all linked to chemicals with endocrine disrupting properties—are as high as US$ 397 billion for the United States and Canada alone.[115]

Studies have linked above average levels of polychlorinated biphenyls (PCBs) to people with Parkinson's, a neurological disorder. PCB's are generally acknowledged to be endocrine disrupting class of chemicals, but this was not the basis for their ban under national laws and global treaties. Due to decades of inaction, these hazardous chemicals persist in our environment. A 2004 study estimated the cost of late action on PCBs in the EU will reach approximately 15 billion Euros from 1970-2018.[116] Estimates of the costs of Parkinson's disease in the United States ranges from $13 billion to $28.5 billion per year.[117]

When including air pollution and arsenic in drinking-water, the global burden of disease amounts to 8.3% of total deaths and 5.7% of the total burden of disease . . . the estimates in the study "undoubtedly underestimate" the real burden of disease . . .

Diabetes in the United States and Canada was estimated to cost $128 billion per year.[118] Neurodevelopmental deficits and thyroid disorders (hypothyroidism) are endemic and amount to US$ 81.5 billion to US$ 167 billion per year for the United States.[119] Autism related costs in the U.S. are approximately US$ 35 billion, and the average yearly medical expenses of individuals with autism are US$ 4,110 – 6,200 greater than those without.[120]

There are various ways of internalizing the costs of hazardous chemicals, from placing the burden of proving the safety of chemicals on their manufacturers, to requiring downstream users of chemicals to collect end-of-life goods containing hazardous chemicals and manage them in an environmentally sound manner.[121] Another example is the Danish Government's tax on PVC and phthalates to internalize the costs of these chemicals on society.[122]

A recent report examining the role of science and principles of governance in maximizing the benefits of innovations and minimizing the harms, recommends internalization of costs to "help level the playing field for less-polluting alternatives.[123] The study suggests several measures, including taxes and charges that would rise or fall in line with new scientific knowledge about potential harms.[124] The report also recommends that firms and governments broaden their accounting systems to incorporate the full impact of their activities on people's health and on ecosystems.[125] Third, the author's recommend prompt and anticipatory no-fault compensation schemes and bonds to offset potential market failures for novel or large-scale technologies and to address difficulties in pursuing claims through the legal system.[126]

Without accurately accounting for these true costs of existing chemical production, use, and disposal, safer alternatives are unable to compete on a level playing field. Measures to internalize the cost of chemicals can be designed to incentivize companies to carry out research into the identification and elimination of hazardous chemicals early in the R&D process, enabling the development and adoption of safer alternatives.[127] Until externalized costs are borne by polluters, safer alternatives will face an uphill battle to displace chemicals of concern with externalized costs.

Stricter laws generate information that is necessary to drive innovation

As exemplified above, awareness of health and safety concerns, together with the likelihood of stricter laws, can accelerate innovation toward safer alternatives. Inventors need access to information about chemical hazards and exposures to develop safer solutions. Regulators need access to hazard and exposure information to restrict the use of hazardous chemicals, enabling the entry of safer alternatives. Consumers and downstream users need access to information about chemicals in products to enable them to choose safer products, thereby incentivizing innovation toward safer alternatives.

Recent experiences also show that the lack of information can impede the development and adoption of safer alternatives. Moreover, these experiences also illustrate how incomplete information on potential alternatives can enable regrettable substitution. For information to accelerate and steer innovation in a safer direction, health and safety information must be generated, and access must be provided to that information.

The vast majority of chemicals lack adequate information about their adverse effects, such as their potential for endocrine disruption.[128] This is due in large part to chemical policies adopted around the world in the 1970s that presumed the safety of nearly all chemicals in commerce. Policies have changed in Europe and elsewhere to require basic information on the most widely used industrial chemicals. For example, 72 % of businesses surveyed responded that REACH had led to increased access to information about chemicals.[129] Small firms benefited more than larger firms in terms of conception of products resulting from increased information enabled by REACH, in particular information about hazardous substances communicated along the supply chain (through Safety Data Sheets).[130]

Despite information generated to date under REACH, the ongoing dearth of information remains a concern. As information is generated in the coming years for "existing" lower production volume chemicals, the benefits of information generated by REACH for innovation is likely to grow.[131]

When the law requires information to be generated about the health and safety of new chemicals, but not existing chemicals, new chemicals face an additional barrier to entry. To the extent that new chemicals are safer than the existing chemicals they hope to displace, these safer chemicals remain at a disadvantage.[132] Although interviews suggest that REACH has not completely eliminated barriers created by greater information requirements for "new" versus "existing" chemicals, REACH has made improvements in this regard. Subsequently, large firms that are major spenders in research and innovation report "a shift of interest to new substances."[133]

To maximize the potential innovation-related benefits of stricter laws that generate new health and safety information, there must be access to this information.

Despite the desire of industry to introduce chemicals as quickly as possible, lowering the requirement for information to be generated about new chemicals would further diminish the ability of regulators to evaluate new chemicals—an ability that Firemaster 550™ and other examples shows to be deficient. As information is generated by REACH and other laws over existing chemicals, the potential for innovation towards safer chemicals will increase.[134]

Because generating information for all chemicals will take several more years under REACH, the Regulation's full potential for innovation is yet to be realized.[135]

To maximize the potential innovation-related benefits of stricter laws that generate new health and safety information, there must be access to this information. For example, a report prepared for the U.S. CPSC noted that it was unable to access all the relevant information it needed to make determinations about the safety of alternatives to phthalates. It found that several toxicity studies on DINCH have been performed, but the results are available only as summaries prepared by the manufacturer.[136] According to the report, the available summaries of these studies are brief and generally insufficient with respect to information on experimental design and results, particularly with regard to quantitative data and dose-response relationships. This is especially troubling given the low-dose effects of the endocrine disrupting phthalates this structurally similar alternative may replace.

Of particular concern to businesses is the need to protect confidential business information (CBI). Respecting the protection of legitimate CBI is a means of encouraging businesses to continue to innovate. Access to information helps to ensure the integrity, efficiency, effectiveness, and accountability of governments, institutions, and industry.[137] However, policy makers have also long recognized the potential for the disclosure of information to promote additional innovation. Patents are based on this principle (see Box 3). Even if regulatory authorities such as CPSC are able to request information provided to other governmental agencies such as U.S. EPA, retailers and consumers are unable to access this and other relevant information to drive innovation to safer alternatives through the power of consumers' preferences.

From national laws (e.g. U.S. TSCA), to regional laws (e.g. EU REACH), to global policy frameworks (SAICM), chemical policies recognize the importance of CBI.[138] The laws that govern toxic chemicals seek to strike a balance between the protection of legitimate confidential business information and ensuring access to certain information that is vital for innovation and public welfare. Regrettably, some laws, such as the U.S. TSCA, still have farther to go in properly balancing these interests.

As part of this balance, these laws and policies recognize that health and safety information should never be CBI.[139] However, despite limits to the type of information that may be claimed as CBI, regulators do not always require justification of claims of confidentiality or re-justification of claims after a period of time.[140] A further problem is the practice of allowing the identity of chemicals that are the subject of health and safety studies to be masked as CBI, impeding the identification which chemical are of concern.[141] Unlike patents, which generally expire after twenty years, CBI can be kept confidential in perpetuity, including inappropriate claims of CBI. The abuse of CBI privileges is well documented, and represents a serious barrier to the identification of hazardous chemicals, and the development and entry of safer alternatives.[142]

Stricter chemical laws can help to pull inventions into the market. But, safer chemicals will continue to face an uphill battle in displacing hazardous chemicals as long as: (1) economies of scale are not addressed; (2) the costs of hazardous chemicals remain externalized on the public; and (3) information asymmetries continue to exist. Effective chemical laws can and must address these factors, enabling the adoption of safer chemicals, and thus innovation towards safer products and processes.

CHAPTER 5

Stricter Chemicals Laws Direct Resources Towards Innovation and the Development of Safer Alternatives

It is argued that strict regulation entails unnecessary costs to the regulated industry, and hampers the introduction of certain inventions. Ideally, inventions not allowed onto the market would be those that are dangerous to human health or the environment, or are otherwise undesirable. Achieving the appropriate balance between measures to protect human health and the environment, on the one hand, and the freedom to experiment and develop better solutions to problems, on the other, is something most stakeholders can agree upon, although where this balance lies is at the center of many contentious debates.

Responding to a survey commissioned by the European Commission about the impacts of EU REACH on innovation (REACH Innovation Report), some businesses claimed that there has been a significant redirection of skilled personnel from R&D and innovation-related activities to compliance work as a result of the implementation of the Regulation.[143] However, since the 1970s, scholars have questioned the notion that stricter laws direct resources away from R&D and innovation-related activities.[144] Scholars conclude from these studies that "innovation is indeed being changed by regulation, but that there is a redirection of innovative efforts into more socially approved areas, rather than an absolute decline."[145] Overall, responses tended to reflect the European Commission's Economic Impact Analysis: negative effects of having to meet compliance requirements could dominate in the short term, with "significant positive impacts on innovation" expected in the longer term.[146]

Other findings of the independent survey suggest that, in fact, more resources have been directed towards innovation as a result of the EU's REACH Regulation. For example, regarding the impact of REACH on innovation, "nearly half of survey respondents report that as a result there has been an increase in expenditure on R&D and related innovative activities."[147] Two reasons were suggested for this increase: the inability to stop innovation programs that were of strategic importance to the firms in question, and—most significantly—*the creation of new opportunities due to the coming into force of the REACH Regulation*.[148]

Scholars conclude from these studies that "innovation is indeed being changed by regulation, but that there is a redirection of innovative efforts into more socially approved areas, rather than an absolute decline."

Of concern during debates over the possible impact of REACH's requirements was the impact of the Regulation on innovation by small and medium-sized enterprises (SMEs). Notably, small, medium and large businesses were all among those reporting an increase in expenditure on R&D in response to the stricter requirements of REACH.[149]

In short, regarding the overall effect of mechanisms within REACH on the willingness and determination of businesses to innovate, the REACH Innovation Report concludes that: "it can be said that despite having to bear the additional costs of REACH, firms have continued to innovate and are keen to continue to do so."[150] Moreover, some of the responses illuminate the potential for the creation of new, highly specialized jobs. As information comes due for submission for an increasing number of chemicals under REACH, it is believed that demand for human resources with technical and regulatory expertise will increase.[151] Universities responded to this new demand by developing chemistry curricula with a specialization in REACH. The authors of the REACH Innovation Report conclude that as a result of REACH "it is envisaged that over time the number and quality . . . of skilled human resources to industry will increase and be supportive of innovative activity."[152]

> ***"It can be said that despite having to bear the additional costs of REACH, firms have continued to innovate and are keen to continue to do so."***

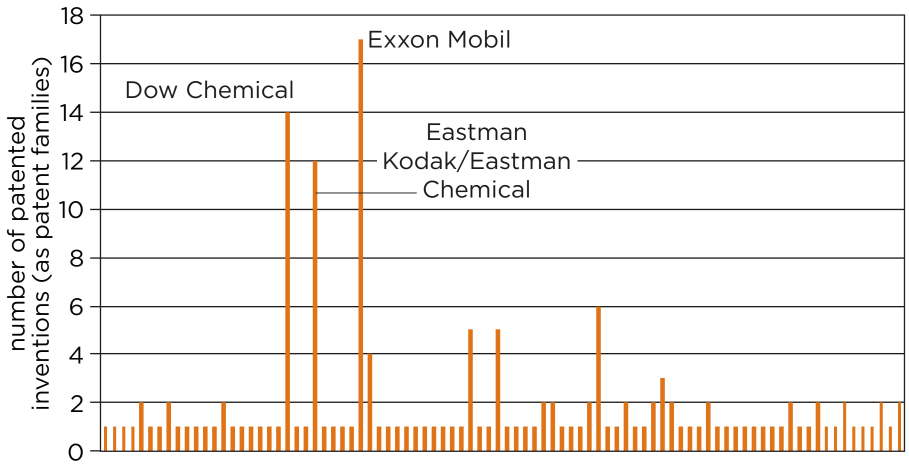
The above patent findings also support the conclusion that stricter rules for chemical safety can drive greater resources towards invention and innovation. The above-mentioned acceleration in the number of patents claiming "non-phthalate or "phthalate-free" inventions is one indication of a redirection of resources towards invention and innovation (Figure 1). Indeed, the most active companies are some of the biggest manufacturers of phthalates—Exxon Mobil, Dow, and Eastman Kodak/Eastman Chemical (Figure 7). In addition to these three large chemical manufactures, 85 other companies obtained at least one patent for a "non-phthalate" or "phthalate-free" invention (Figure 7).

The most common phthalate measure restricts six phthalates above a certain concentration in toys and children's products. However, approximately 95% of the patents identified were not limited to infant and children's products (Figure 8). Moreover, inventions were disclosed for the use of phthalates in a range of products, much broader than the limited market segment singled out under the law. These patent filings suggest that as the likelihood of stricter rules over existing chemicals of concern increased, resources were devoted to innovation to maintain or even capture market share.

Thus, while some may argue that stricter rules for ensuring chemical safety may direct resources away from innovation, recent experiences suggest that the desire to maintain market share by industry is sufficient to direct resources towards the innovation of safer alternatives, and the development of new, innovation-friendly skills.

FIGURE 7

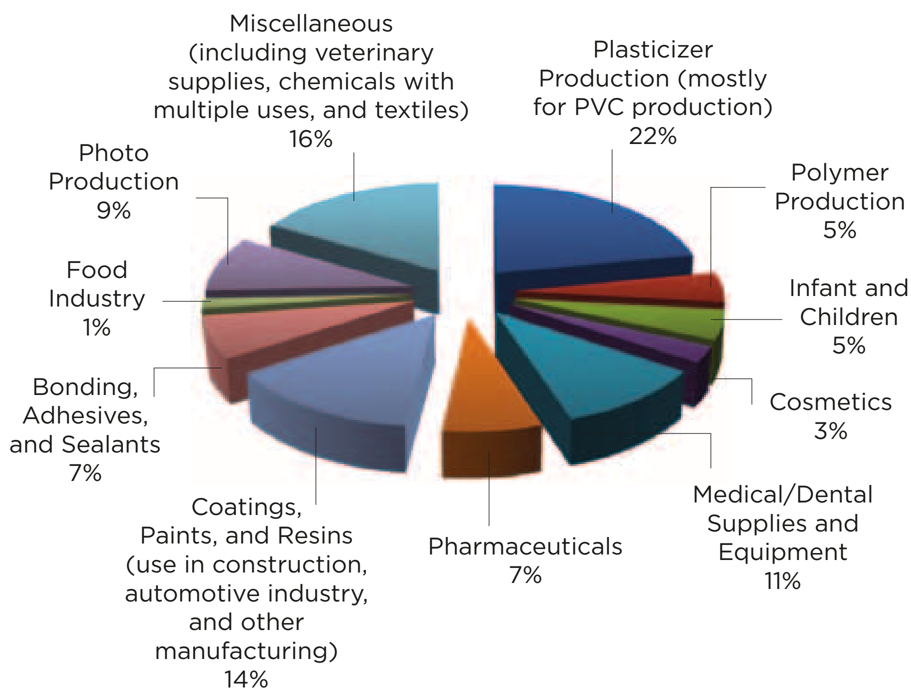
Nearly 100 Companies Patented an Alternative to Hazardous Phthalates



85 companies filed a patent for an invention for an alternative to phthalates between 1972 and 2011, led by Exxon Mobil, Dow Chemical and Eastman Chemical (Eastman Kodak) in response to stricter laws as illustrated in Figures 2and 3.

FIGURE 8

Classes of Products for Patented Phthalate-free Inventions



Most patented inventions for non-phthalate products as disclosed in patent filings between 1972–2011 went beyond just those product classes initially singled out by legislation.

CHAPTER 6

Conclusions and Recommendations for Policy-Makers

Consumers, downstream users and investors are increasingly demanding products free of hazardous chemicals throughout their life-cycle. In addition to customer demand, businesses increasingly recognize that the transition away from hazardous chemicals is often accompanied with the emergence of a competitive advantage and market opportunities. Effective chemical policies must be in place to reward businesses that develop safer approaches by enabling their ideas to replace those that are less safe.

The question is then how to spur the innovation of approaches that stand to provide the most improvement to people, wildlife and the environment from the status quo of chemicals. And then, for those inventions that are indeed a safer alternative, how to effectively overcome barriers to entry so that these safer alternatives can displace incumbent hazardous chemicals and production processes in the marketplace.

Our findings suggest that progressively stricter laws, with a gradual phase-out of chemicals with certain intrinsic hazards, spur the invention of alternatives, with the potential to pull safer alternatives into the market, enabling them to overcome barriers to entry. This enables innovators that seek comparative advantages to continuously innovate towards the safest alternative for various uses, and allows predictability for industry and investors.

With these questions and findings in mind, the following recommendations are made for policymakers around the world.

1. Ensure the burden of proving chemical safety falls on chemical manufacturers.

A fundamental first step to chemical safety is to ensure that industry generates information demonstrating that both new and existing chemicals are safe, instead of placing the burden on public authorities with limited resources and, in some cases, limited authority to compel the production of information. Requiring that chemical manufacturers generate information on intrinsic hazards of both existing as well as new chemicals levels the playing field for new chemicals and enables a more meaningful assessment of alternatives. This information enables regulators to remove entrenched chemicals of concern, downstream users to deselect hazardous chemicals from their supply chain, and chemical manufacturers to innovate towards safer alternatives.

Some of the burden of generating this information for certain markets now falls on the regulated industry but serious gaps remain,[153] particularly in relation to the endocrine disrupting properties of chemicals in commerce. As part of the burden of proving a chemical is safe, chemical laws should require chemical manufacturers to provide sufficient information to ensure that a chemical does not have endocrine disrupting properties.

2. Phase-out chemicals with certain intrinsic hazards.

While the REACH Candidate List and other similar measures alert consumers and businesses to chemicals of concern, simply relying upon the identification of hazardous chemicals through lists is insufficient. Government authorities must also possess—and exercise—the power to remove hazardous chemicals from the market based on their intrinsic hazards. As hazardous chemicals are removed, the generation of adequate data on both new and existing chemicals can help to ensure that "regrettable substitutes" are avoided.

3. Recognize endocrine disruption as an intrinsic hazard that cannot be soundly managed.

Endocrine disruption is an intrinsic hazard of certain chemicals, linked to myriad of adverse effects that have been on the rise over the past several decades. As there is no safe dose of exposure to endocrine disrupting chemicals (EDCs), they should be recognized as a distinct category of chemicals that needs to be phased out globally, similarly to other chemicals with intrinsic hazards such as persistence and bioaccumulation, carcinogenicity, mutagenicity, or toxicity to reproduction.

Regulators must develop broad criteria to identify EDCs. Should criteria be defined too narrowly, many chemicals with endocrine disrupting properties risk exclusion from the provisions of laws designed to protect human health and the environment.

4. Internalize the costs of hazardous chemicals.

The law must ensure that all externalized costs relating to the production, use and disposal of hazardous chemicals are internalized by the chemical industry. Not only would this lead downstream users to shift to alternatives with lower costs, but this would in turn incentivize chemical manufacturers to invest in research and development of safer alternatives.

5. Promote access to information.

The laws that govern toxic chemicals seek to strike a balance between the protection of legitimate confidential business information to incentivize innovation, and ensuring access to certain information that is vital for developing effective laws and ensuring public welfare.

Policy makers should ensure that health and safety information is generated and made available. Claims of confidentiality should be justified, periodically re-justified, and never granted for health and safety information, to enable the development of safer alternatives.

Chemical laws should facilitate business and consumer awareness of hazardous chemicals throughout the supply chain. This encourages businesses to eliminate chemicals of concern from their supply chains, driving businesses upstream to discover, develop and improve alternatives. Policy makers can make use of simple but effective measures to inform downstream users and consumers about products containing chemicals of concern.

First, the use of generic terms, such as "PBT," "CMR," or "EDC"—along with supportive education and awareness-raising efforts—can alert consumers to potential hazards without requiring consumers to navigate a technical list of chemical ingredients, while preserving the confidentiality of business information.

Second, governments can capitalize on the widespread use of mainstream technology, in particular smart phones and tablets, for disseminating reliable and easily understandable information about the lifecycle of products. Consumers in many countries are already able to scan in barcodes to be told whether or not a product contains hazardous chemicals, including some EDCs. Where labels on product packaging can only convey a limited amount of information, these platforms have the potential to provide valuable information to the public and businesses, to varying degrees of detail.

6. Craft stronger international laws to ensure a level playing field at the global level.

Chemical production, use and disposal continue to expand globally, fastest in developing countries. In an increasingly interconnected, globalized world, the need for strong international standards for chemical safety is apparent. Only a narrow sliver of chemicals of concern on the market are covered under legally binding global treaties throughout their life-cycle. A broader international regime to cover a wider range of hazardous chemicals and chemical-related risks is required to create a level playing field for businesses operating in a globalized world.

Endnotes

1 UN Environment Programme (UNEP), *Global Chemicals Outlook* (2012), available at: *http://www.unep.org/pdf/GCO_Synthesis%20Report_CBDTIE_UNEP_September5_2012.pdf*; Organisation for Economic Cooperation and Development (OECD), *Environmental Outlook for the Chemicals Industry* (2001), available at: *http://www.oecd.org/dataoecd/7/45/2375538.pdf*. Inflation-adjusted dollars derived from U.S. Bureau of Labor Statistics, *CPI Inflation Calculator* (2012), available at: *http://www.bls.gov/data/inflation_calculator.htm*.

2 In this report, we adopt the definition of innovation used in the Oslo Manual: "an innovation is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations." OECD/European Commission, *Oslo Manual: Guidelines for collecting and interpreting innovation data*, p.46 (2005).

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26 *See* ECHA, *Authorisation List*, available at: *http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list*
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42 Reach Innovation Report, *supra* n. 37, pg vii.
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153 In recent years, Europe has led the world in ensuring that those who profit from the use of chemicals bear the burden of proving that their chemicals are safe for their intended uses. The EU's REACH regulation reversed the burden of proving the safety of industrial chemicals from governments to industry, and identifies to downstream users and consumers certain chemicals of concern, providing a clear direction to innovation—towards safer chemicals. Other countries, such as Australia, Canada, China, Japan, South Korea, Switzerland, and Turkey are following suit. However, many other countries, including the United States, are yet to adopt similar policies. Even in Europe, the burden still remains on public authorities for chemicals produced below a certain amount, and chemicals on the REACH Candidate List for which a "Restriction" is sought.

DRIVING INNOVATION

How stronger laws help bring safer chemicals to market

Are innovation and the law at odds? A closer look shows that stricter laws over hazardous chemicals help to drive innovation in chemical and product sectors. This study shows how progressively stricter laws spur the innovation of safer alternatives and can pull safer alternatives into the market, enabling them to overcome barriers to entry. But, policies must be in place to ensure that alternatives do not also have intrinsic hazards, to better ensure that innovation creates a safer marketplace.

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